



Australian Government

Department of Health

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 April 2015

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 April 2015. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 April 2015 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.76
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.80
	Allowable additional patient charge*	\$4.27
Additional Fees (for safety net prices):	Ready-prepared	\$1.15
	Extemporaneously-prepared	\$1.50
Patient Co-payments:	General	\$37.70
	Concessional	\$6.10
Safety Net Thresholds:	General	\$1453.90
	Concessional	\$366.00
Safety Net Card Issue Fee:		\$9.47

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

Prescriber Bag

Additions

Addition – Item

- 10244E **DIPHTHERIA TOXOID + TETANUS TOXOID**, diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials (*MassBiologics tetanus and diphtheria toxoids adsorbed*)
- 10251M **OXYTOCIN**, oxytocin 10 international units/mL injection, 5 x 1 mL ampoules (*Oxytocin Sandoz*)

Deletions

Deletion – Item

- 3491R **TERBUTALINE**, terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules (*Bricanyl*)

Alterations

Alteration – Maximum Quantity

- | | | | |
|-------|---|------------|---------|
| 3486L | BENZYL PENICILLIN , benzylpenicillin 600 mg injection, 1 x 600 mg vial (<i>BenPen</i>) | From
10 | To
5 |
|-------|---|------------|---------|

General Pharmaceutical Benefits

Additions

Addition – Item

- 10238W **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (*Cimzia*)
- 10234P **DESVENLAFAXINE**, desvenlafaxine 50 mg tablet: modified release, 28 tablets (*Desvenlafaxine GH XR*)
- 10241B **DESVENLAFAXINE**, desvenlafaxine 50 mg tablet: modified release, 28 tablets (*Desfax, Desvenlafaxine Actavis*)
- 10231L **DESVENLAFAXINE**, desvenlafaxine 100 mg tablet: modified release, 28 tablets (*Desfax, Desvenlafaxine Actavis*)
- 10245F **DESVENLAFAXINE**, desvenlafaxine 100 mg tablet: modified release, 28 tablets (*Desvenlafaxine GH XR*)
- 10229J **IRON SUCROSE**, iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules (*Venofer*)
- 10254Q **MESALAZINE**, mesalazine 4 g granules: modified release, 30 sachets (*Pentasa*)
- 10226F **SORAFENIB**, sorafenib 200 mg tablet, 60 (*Nexavar*)
- 10242C **SORAFENIB**, sorafenib 200 mg tablet, 60 (*Nexavar*)
- 10250L **SUCROFERRIC OXYHYDROXIDE**, iron (as sucroferic oxyhydroxide) 500 mg tablet: chewable, 90 (*Velphoro*)

Addition – Brand

- 9012H *APO-Alendronate Plus D3 70 mg/70 mcg, TX – ALENDRONATE + COLECALCIFEROL*, alendronate 70 mg + colecalciferol 70 microgram tablet, 4
- 9012H *Alendronate D3 70 mg/70 microgram, UA – ALENDRONATE + COLECALCIFEROL*, alendronate 70 mg + colecalciferol 70 microgram tablet, 4
- 9183H *APO-Alendronate Plus D3 70 mg/140 mcg, TX – ALENDRONATE + COLECALCIFEROL*, alendronate 70 mg + colecalciferol 140 microgram tablet, 4
- 9183H *Alendronate D3 70 mg/140 microgram, UA – ALENDRONATE + COLECALCIFEROL*, alendronate 70 mg + colecalciferol 140 microgram tablet, 4
- 9351E *Alendronate Plus D3 Calcium Actavis, UA – ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE*, alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack
- 9351E *Alendronate Plus D3 and Calcium Sandoz, SZ – ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE*, alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack
- 9351E *ReddyMax Plus D-Cal, RZ – ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE*, alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack
- 2600W *APO-Allopurinol, TX – ALLOPURINOL*, allopurinol 100 mg tablet, 200
- 2604C *APO-Allopurinol, TX – ALLOPURINOL*, allopurinol 300 mg tablet, 60
- 2343H *Amiodarone Actavis, GN – AMIODARONE*, amiodarone hydrochloride 200 mg tablet, 30
- 2417F *APO-Amitriptyline 10, TX – AMITRIPTYLINE*, amitriptyline hydrochloride 10 mg tablet, 50
- 2417F *Chem mart Amitriptyline, CH – AMITRIPTYLINE*, amitriptyline hydrochloride 10 mg tablet, 50
- 2417F *Terry White Chemists Amitriptyline, TW – AMITRIPTYLINE*, amitriptyline hydrochloride 10 mg tablet, 50
- 2418G *APO-Amitriptyline 25, TX – AMITRIPTYLINE*, amitriptyline hydrochloride 25 mg tablet, 50
- 2418G *Chem mart Amitriptyline, CH – AMITRIPTYLINE*, amitriptyline hydrochloride 25 mg tablet, 50
- 2418G *Terry White Chemists Amitriptyline, TW – AMITRIPTYLINE*, amitriptyline hydrochloride 25 mg tablet, 50
- 2429W *APO-Amitriptyline 50, TX – AMITRIPTYLINE*, amitriptyline hydrochloride 50 mg tablet, 50
- 2429W *Chem mart Amitriptyline, CH – AMITRIPTYLINE*, amitriptyline hydrochloride 50 mg tablet, 50
- 2429W *Terry White Chemists Amitriptyline, TW – AMITRIPTYLINE*, amitriptyline hydrochloride 50 mg tablet, 50
- 2751T *Amlodipine AN, EA – AMLODIPINE*, amlodipine 5 mg tablet, 30
- 2752W *Amlodipine AN, EA – AMLODIPINE*, amlodipine 10 mg tablet, 30
- 1892N *APO-Amoxycillin and Clavulanic Acid 125/31.25, TX – AMOXYCILLIN + CLAVULANIC ACID*, amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL
- 5009P *APO-Amoxycillin and Clavulanic Acid 125/31.25, TX – AMOXYCILLIN + CLAVULANIC ACID*, amoxycillin 125 mg/5 mL + clavulanic

	acid 31.25 mg/5 mL oral liquid: powder for, 75 mL (Dental)
5011R	<i>APO-Amoxycillin and Clavulanic Acid 400/57, TX</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL (Dental)
8319W	<i>APO-Amoxycillin and Clavulanic Acid 400/57, TX</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL
8213G	<i>Blooms the Chemist Atorvastatin, IB</i> – ATORVASTATIN , atorvastatin 10 mg tablet, 30
9230T	<i>Blooms the Chemist Atorvastatin, IB</i> – ATORVASTATIN , atorvastatin 10 mg tablet, 30
2730Q	<i>Terry White Chemists Baclofen, TW</i> – BACLOFEN , baclofen 25 mg tablet, 100
8220P	<i>Citalopram Actavis, VN</i> – CITALOPRAM , citalopram 20 mg tablet, 28
5541P	<i>Trusamide, QA</i> – DORZOLAMIDE , dorzolamide 2% (20 mg/mL) eye drops, 5 mL (Optometrical)
8488R	<i>Trusamide, QA</i> – DORZOLAMIDE , dorzolamide 2% (20 mg/mL) eye drops, 5 mL
2373X	<i>Herron ClearLax, ON</i> – MACROGOL-3350 , macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets
8228C	<i>Ikotab, QA</i> – NICORANDIL , nicorandil 10 mg tablet, 60
8229D	<i>Ikotab, QA</i> – NICORANDIL , nicorandil 20 mg tablet, 60
3050M	<i>Blooms the Chemist Perindopril, IB</i> – PERINDOPRIL , perindopril erbumine 2 mg tablet, 30
3051N	<i>Blooms the Chemist Perindopril, IB</i> – PERINDOPRIL , perindopril erbumine 4 mg tablet, 30
8704D	<i>Blooms the Chemist Perindopril, IB</i> – PERINDOPRIL , perindopril erbumine 8 mg tablet, 30
8363E	<i>Raloxifene AN, EA</i> – RALOXIFENE , raloxifene hydrochloride 60 mg tablet, 28
1316G	<i>Ramipril Winthrop, WA</i> – RAMIPRIL , ramipril 10 mg tablet, 30
1977C	<i>Ranitidine GH, GQ</i> – RANITIDINE , ranitidine 300 mg tablet, 30
1849H	<i>Iptam, AL</i> – SUMATRIPTAN , sumatriptan 50 mg tablet, 4
8144P	<i>Iptam, AL</i> – SUMATRIPTAN , SUMATRIPTAN Tablet 50 mg (as succinate), 2
8448P	<i>Ursosan, BZ</i> – URSODEOXYCHOLIC ACID , ursodeoxycholic acid 250 mg capsule, 100

Addition – Equivalence Indicator

2417F	<i>Endep 10, AF</i> – AMITRIPTYLINE , amitriptyline hydrochloride 10 mg tablet, 50
2418G	<i>Endep 25, AF</i> – AMITRIPTYLINE , amitriptyline hydrochloride 25 mg tablet, 50
2429W	<i>Endep 50, AF</i> – AMITRIPTYLINE , amitriptyline hydrochloride 50 mg tablet, 50
9366Y	<i>Pristiq, PF</i> – DESVENLAFAXINE , desvenlafaxine 50 mg tablet: modified release, 28 tablets
9367B	<i>Pristiq, PF</i> – DESVENLAFAXINE , desvenlafaxine 100 mg tablet: modified release, 28 tablets
5541P	<i>Trusopt, MK</i> – DORZOLAMIDE , dorzolamide 2% (20 mg/mL) eye drops, 5 mL (Optometrical)
8488R	<i>Trusopt, MK</i> – DORZOLAMIDE , dorzolamide 2% (20 mg/mL) eye drops, 5 mL
8228C	<i>Ikorel, SW</i> – NICORANDIL , nicorandil 10 mg tablet, 60
8229D	<i>Ikorel, SW</i> – NICORANDIL , nicorandil 20 mg tablet, 60
8448P	<i>Ursosalk, OA</i> – URSODEOXYCHOLIC ACID , ursodeoxycholic acid 250 mg capsule, 100

Deletions

Deletion – Item

1575X	FOLINIC ACID , folinic acid 50 mg/5 mL injection, 5 x 5 mL ampoules (<i>Calcium Folate Ebewe</i>)
2710P	MIFEPRISTONE , mifepristone 200 mg tablet, 1 (<i>Mifepristone Linepharma</i>)
2672P	MISOPROSTOL , misoprostol 200 microgram tablet, 4 (<i>GyMiso</i>)
2681D	POLYVINYL ALCOHOL , polyvinyl alcohol 3% eye drops, 15 mL (<i>Liquifilm Forte, PVA Forte</i>)
5525T	POLYVINYL ALCOHOL , polyvinyl alcohol 3% eye drops, 15 mL (<i>Liquifilm Forte, PVA Forte</i>) (Optometrical)
9222J	POLYVINYL ALCOHOL , polyvinyl alcohol 3% eye drops, 15 mL (<i>Liquifilm Forte, PVA Forte</i>)
2995P	SALCATONIN , salcatonin 50 international units/mL injection, 5 x 1 mL ampoules (<i>Miacalcic 50</i>)

Deletion – Brand

1147J	<i>APO-Captopril, TX</i> – CAPTOPRIL , captopril 12.5 mg tablet, 90
1148K	<i>APO-Captopril, TX</i> – CAPTOPRIL , captopril 25 mg tablet, 90
1149L	<i>APO-Captopril, TX</i> – CAPTOPRIL , captopril 50 mg tablet, 90
3162K	<i>Diazepam-GA, GN</i> – DIAZEPAM , diazepam 5 mg tablet, 50
5072Y	<i>Diazepam-GA, GN</i> – DIAZEPAM , diazepam 5 mg tablet, 50 (Dental)
8600P	<i>Esomeprazole Actavis, GN</i> – ESOMEPRAZOLE , esomeprazole 20 mg tablet: enteric, 30 tablets
8886Q	<i>Esomeprazole Actavis, GN</i> – ESOMEPRAZOLE , esomeprazole 20 mg tablet: enteric, 30 tablets
3401B	<i>Esomeprazole Actavis, GN</i> – ESOMEPRAZOLE , esomeprazole 40 mg tablet: enteric, 30 tablets
8601Q	<i>Esomeprazole Actavis, GN</i> – ESOMEPRAZOLE , esomeprazole 40 mg tablet: enteric, 30 tablets
2373X	<i>MediHealth ClearLax, ON</i> – MACROGOL-3350 , macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets

Alterations

Alteration – Item Description

From

2639X	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE , amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL pouches (<i>HCU cooler 10</i>)
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To

2639X	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE , amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets (<i>HCU cooler 10</i>)
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From

2640Y	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE , amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL pouches (<i>HCU cooler 20</i>)
To	
2640Y	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE , amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets (<i>HCU cooler 20</i>)
From	
2674R	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE , amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL pouches (<i>TYR cooler 10</i>)
To	
2674R	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE , amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL sachets (<i>TYR cooler 10</i>)
From	
2701E	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE , amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL pouches (<i>TYR cooler 20</i>)
To	
2701E	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE , amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL sachets (<i>TYR cooler 20</i>)

Alteration – Brand Name

From	
1891M	<i>Amoxiclav AN 500/125, EA</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10
To	
1891M	<i>Amoxiclav AN 500/125, EA</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10
From	
5008N	<i>Amoxiclav AN 500/125, EA</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10 (Dental)
To	
5008N	<i>Amoxiclav AN 500/125, EA</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10 (Dental)
From	
5006L	<i>Amoxiclav AN 875/125, EA</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10 (Dental)
To	
5006L	<i>Amoxiclav AN 875/125, EA</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10 (Dental)
From	
8254K	<i>Amoxiclav AN 875/125, EA</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10
To	
8254K	<i>Amoxiclav AN 875/125, EA</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10
From	
1655D	<i>APOTEX-MORPHINE MR, TX</i> – MORPHINE , morphine sulfate 60 mg tablet: modified release, 28 tablets
To	
1655D	<i>MORPHINE MR APOTEX, TX</i> – MORPHINE , morphine sulfate 60 mg tablet: modified release, 28 tablets

Changes to Restrictions

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

9033K	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Humira</i>)
9034L	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Humira</i>)
9101B	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
9102C	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
10011X	DAPAGLIFLOZIN , dapagliflozin 10 mg tablet, 28 (<i>Forxiga</i>)
9366Y	DESVENLAFAXINE , desvenlafaxine 50 mg tablet: modified release, 28 tablets (<i>Pristiq</i>)
9367B	DESVENLAFAXINE , desvenlafaxine 100 mg tablet: modified release, 28 tablets (<i>Pristiq</i>)
10202Y	EMPAGLIFLOZIN , empagliflozin 10 mg tablet, 30 (<i>Jardiance</i>)
10206E	EMPAGLIFLOZIN , empagliflozin 25 mg tablet, 30 (<i>Jardiance</i>)
9035M	ETANERCEPT , etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
9036N	ETANERCEPT , etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
9087G	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Enbrel</i>)
9088H	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Enbrel</i>)
9457R	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Enbrel</i>)
9458T	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Enbrel</i>)
10131F	EVEROLIMUS , everolimus 5 mg tablet, 30 (<i>Afinitor</i>)
10132G	EVEROLIMUS , everolimus 10 mg tablet, 30 (<i>Afinitor</i>)
10133H	EVEROLIMUS , everolimus 5 mg tablet, 30 (<i>Afinitor</i>)
10135K	EVEROLIMUS , everolimus 10 mg tablet, 30 (<i>Afinitor</i>)
3423E	EXENATIDE , exenatide 5 microgram/0.02 mL injection, 60 unit doses (<i>Byetta 5 microgram</i>)
3424F	EXENATIDE , exenatide 10 microgram/0.04 mL injection, 60 unit doses (<i>Byetta 10 microgram</i>)
1610R	FOLINIC ACID , folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules (<i>Leucovorin Calcium (Pfizer Australia Pty Ltd)</i>)
8740B	FOLINIC ACID , folinic acid 50 mg/5 mL injection, 1 x 5 mL vial (<i>Leucovorin Calcium (Hospira Pty Limited)</i>)
3430M	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe (<i>Simponi</i>)
3431N	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe (<i>Simponi</i>)
3432P	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe (<i>Simponi</i>)

3433Q	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe (<i>Simponi</i>)
8807M	IRON SUCROSE , iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules (<i>Venofer</i>)
9403X	LANTHANUM , LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90 (<i>Fosrenol</i>)
9404Y	LANTHANUM , LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90 (<i>Fosrenol</i>)
9405B	LANTHANUM , LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90 (<i>Fosrenol</i>)
2142R	SEVELAMER , sevelamer hydrochloride 800 mg tablet, 180 (<i>Renagel</i>)
10004M	SUNITINIB , sunitinib 12.5 mg capsule, 28 (<i>Sutent</i>)
10009T	SUNITINIB , sunitinib 12.5 mg capsule, 28 (<i>Sutent</i>)
10010W	SUNITINIB , sunitinib 50 mg capsule, 28 (<i>Sutent</i>)
2837H	SUNITINIB , sunitinib 50 mg capsule, 28 (<i>Sutent</i>)
2842N	SUNITINIB , sunitinib 25 mg capsule, 28 (<i>Sutent</i>)
2959R	SUNITINIB , sunitinib 25 mg capsule, 28 (<i>Sutent</i>)
5469W	VARENICLINE , varenicline 1 mg tablet, 56 (<i>Champix</i>)

Alteration – Restriction Level

		<i>From</i>	<i>To</i>
10202Y	EMPAGLIFLOZIN , empagliflozin 25 mg tablet, 30 (<i>Jardiance</i>)	authority-required	streamlined
10206E	EMPAGLIFLOZIN , empagliflozin 10 mg tablet, 30 (<i>Jardiance</i>)	authority-required	streamlined

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
1266P	<i>Cycloblastin</i> – CYCLOPHOSPHAMIDE , cyclophosphamide 50 mg tablet, 50	PF	ZX
8646C	<i>Prograf</i> – TACROLIMUS , tacrolimus 500 microgram capsule, 100	JC	LL
5299X	<i>Prograf XL</i> – TACROLIMUS , tacrolimus 500 microgram capsule: modified release, 30 capsules	JC	LL
8647D	<i>Prograf</i> – TACROLIMUS , tacrolimus 1 mg capsule, 100	JC	LL
5300Y	<i>Prograf XL</i> – TACROLIMUS , tacrolimus 1 mg capsule: modified release, 60 capsules	JC	LL
8648E	<i>Prograf</i> – TACROLIMUS , tacrolimus 5 mg capsule, 50	JC	LL
5451X	<i>Prograf XL</i> – TACROLIMUS , tacrolimus 5 mg capsule: modified release, 30 capsules	JC	LL

Advance Notices

1 May 2015

Deletion – Brand

2058H	<i>Artelac, BU</i> – CARBOMER + TRIGLYCERIDE LIPIDS , carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses
2090B	<i>Artelac, BU</i> – CARBOMER + TRIGLYCERIDE LIPIDS , carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses (Optometrical)
1171P	<i>Chloromycetin, PF</i> – CHLORAMPHENICOL , chloramphenicol 1% eye ointment, 4 g
5511C	<i>Chloromycetin, PF</i> – CHLORAMPHENICOL , chloramphenicol 1% eye ointment, 4 g (Optometrical)
1473M	<i>Fluconazole-Clarix, AE</i> – FLUCONAZOLE , fluconazole 100 mg/50 mL injection, 1 x 50 mL vial
1474N	<i>Fluconazole-Clarix, AE</i> – FLUCONAZOLE , fluconazole 200 mg/100 mL injection, 1 x 100 mL vial
2412Y	<i>Frusemide AN, EA</i> – FRUSEMIDE , frusemide 40 mg tablet, 100
2414C	<i>Frusemide AN, EA</i> – FRUSEMIDE , frusemide 20 mg tablet, 100
8534E	<i>Lercanidipine AN, EA</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
8679T	<i>Lercanidipine AN, EA</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
1627P	<i>Tolvon, MK</i> – MIANSERIN , mianserin hydrochloride 10 mg tablet, 50
1742Q	<i>Vagifem, NO</i> – OESTRADIOL , oestradiol 25 microgram pessary: modified release, 15
9004X	<i>Reandron 1000, BN</i> – TESTOSTERONE UNDECANOATE , testosterone undecanoate 1 g/4 mL injection, 1 x 4 mL ampoule

1 June 2015

Deletion – Brand

1172Q	<i>Chloromycetin, PF</i> – CHLORAMPHENICOL , chloramphenicol 0.5% ear drops, 5 mL
1210Q	<i>Ciproxin 750, BN</i> – CIPROFLOXACIN , ciprofloxacin 750 mg tablet, 14

1 July 2015

Deletion – Brand

1783W	<i>Ceftriaxone ICP, PP</i> – CEFTRIAXONE , ceftriaxone 500 mg injection, 1 x 500 mg vial
9058R	<i>Ceftriaxone ICP, PP</i> – CEFTRIAXONE , ceftriaxone 500 mg injection, 1 x 500 mg vial

1 August 2015

Deletion – Brand

2873F	<i>Invokana, JC</i> – CANAGLIFLOZIN , canagliflozin 100 mg tablet, 30
2987F	<i>Invokana, JC</i> – CANAGLIFLOZIN , canagliflozin 300 mg tablet, 30
9157Y	<i>Sensipar, AN</i> – CINACALCET , cinacalcet 30 mg tablet, 28
9158B	<i>Sensipar, AN</i> – CINACALCET , cinacalcet 60 mg tablet, 28
9159C	<i>Sensipar, AN</i> – CINACALCET , cinacalcet 90 mg tablet, 28

Palliative Care

Additions

Addition – Brand

2351R *Herron ClearLax, ON – MACROGOL-3350*, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets
 2353W *Herron ClearLax, ON – MACROGOL-3350*, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets

Deletions

Deletion – Brand

5356X *Diazepam-GA, GN – DIAZEPAM*, diazepam 5 mg tablet, 50
 5358B *Diazepam-GA, GN – DIAZEPAM*, diazepam 5 mg tablet, 50
 2351R *MediHealth ClearLax, ON – MACROGOL-3350*, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets
 2353W *MediHealth ClearLax, ON – MACROGOL-3350*, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

10228H **ALEMTUZUMAB**, alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial (*Lemtrada*)
 10232M **ALEMTUZUMAB**, alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial (*Lemtrada*)
 10227G **APOMORPHINE**, apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules (*Apomine*)
 10247H **DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE**, dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30 (*Triumeq*)
 10233N **SUCROFERRIC OXYHYDROXIDE**, iron (as sucroferriic oxyhydroxide) 500 mg tablet: chewable, 90 (*Velphoro*)

Addition – Brand

9547L *Sildenafil AN PHT 20, EA – SILDENAFIL*, sildenafil 20 mg tablet, 90

Alterations

Changes to Restrictions

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

5609F **APOMORPHINE**, apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules (*Apomine*)
 5610G **APOMORPHINE**, apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules (*Apomine*)
 5611H **APOMORPHINE**, apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes (*Apomine PFS*)
 5756Y **INFLIXIMAB**, infliximab 100 mg injection, 1 x 100 mg vial (*Remicade*)
 5780F **LANTHANUM**, LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90 (*Fosrenol*)
 5781G **LANTHANUM**, LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90 (*Fosrenol*)
 5782H **LANTHANUM**, LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90 (*Fosrenol*)
 9546K **SEVELAMER**, sevelamer hydrochloride 800 mg tablet, 180 (*Renagel*)

Alteration – Manufacturer Code

		From	To
9558C	<i>Prograf</i> – TACROLIMUS , tacrolimus 500 microgram capsule, 100	JC	LL
9664P	<i>Prograf XL</i> – TACROLIMUS , tacrolimus 500 microgram capsule: modified release, 30 capsules	JC	LL
9560E	<i>Prograf</i> – TACROLIMUS , tacrolimus 1 mg capsule, 100	JC	LL
9665Q	<i>Prograf XL</i> – TACROLIMUS , tacrolimus 1 mg capsule: modified release, 60 capsules	JC	LL
9561F	<i>Prograf</i> – TACROLIMUS , tacrolimus 5 mg capsule, 50	JC	LL
9666R	<i>Prograf XL</i> – TACROLIMUS , tacrolimus 5 mg capsule: modified release, 30 capsules	JC	LL

Advance Notices

1 August 2015

Deletion – Brand

5621W *Sensipar, AN – CINACALCET*, cinacalcet 30 mg tablet, 28
 5622X *Sensipar, AN – CINACALCET*, cinacalcet 60 mg tablet, 28
 5623Y *Sensipar, AN – CINACALCET*, cinacalcet 90 mg tablet, 28

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

10243D **ALEMTUZUMAB**, alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial (*Lemtrada*)
 10246G **ALEMTUZUMAB**, alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial (*Lemtrada*)

10235Q	APOMORPHINE , apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules (<i>Apomine</i>)
10248J	DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE , dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30 (<i>Triumeq</i>)
10230K	SUCROFERRIC OXYHYDROXIDE , iron (as sucroferic oxyhydroxide) 500 mg tablet: chewable, 90 (<i>Velphoro</i>)

Addition – Brand

9605M	<i>Sildenafil AN PHT 20, EA</i> – SILDENAFIL , sildenafil 20 mg tablet, 90
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Alterations

Changes to Restrictions

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

9607P	APOMORPHINE , apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules (<i>Apomine</i>)
9640J	APOMORPHINE , apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules (<i>Apomine</i>)
9647R	APOMORPHINE , apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes (<i>Apomine PFS</i>)
6496X	INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial (<i>Remicade</i>)
9635D	LANTHANUM , LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90 (<i>Fosrenol</i>)
9636E	LANTHANUM , LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90 (<i>Fosrenol</i>)
9637F	LANTHANUM , LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90 (<i>Fosrenol</i>)
9620H	SEVELAMER , sevelamer hydrochloride 800 mg tablet, 180 (<i>Renagel</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
6328C	<i>Prograf</i> – TACROLIMUS , tacrolimus 500 microgram capsule, 100	JC	LL
9681M	<i>Prograf XL</i> – TACROLIMUS , tacrolimus 500 microgram capsule: modified release, 30 capsules	JC	LL
6216E	<i>Prograf</i> – TACROLIMUS , tacrolimus 1 mg capsule, 100	JC	LL
9682N	<i>Prograf XL</i> – TACROLIMUS , tacrolimus 1 mg capsule: modified release, 60 capsules	JC	LL
6217F	<i>Prograf</i> – TACROLIMUS , tacrolimus 5 mg capsule, 50	JC	LL
9683P	<i>Prograf XL</i> – TACROLIMUS , tacrolimus 5 mg capsule: modified release, 30 capsules	JC	LL

Advance Notices

1 August 2015

Deletion – Brand

9625N	<i>Sensipar, AN</i> – CINACALCET , cinacalcet 30 mg tablet, 28
9626P	<i>Sensipar, AN</i> – CINACALCET , cinacalcet 60 mg tablet, 28
9627Q	<i>Sensipar, AN</i> – CINACALCET , cinacalcet 90 mg tablet, 28

Botulinum Toxin Program

Additions

Addition – Item

10253P	INCOBOTULINUMTOXINA , incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial (<i>Xeomin</i>)
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Alterations

Alteration – Restriction

6103F	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 x 100 units vial (<i>Botox</i>)
1152P	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 x 300 units vial (<i>Dysport</i>)
6293F	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 x 500 units vial (<i>Dysport</i>)

PREScriBER BAG

			Dispensed Price for Max. Qty		
Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	\$	Brand Name and Manufacturer	
DIPHTHERIA TOXOID + TETANUS TOXOID					
<u>Note</u>					
For immunisation of adults and children aged greater than or equal to 8 years.					
10244E NP	diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials	1	144.59	MassBiologics tetanus and diphtheria toxoids adsorbed	CS
OXYTOCIN					
10251M	oxytocin 10 international units/mL injection, 5 x 1 mL ampoules	1	61.76	Oxytocin Sandoz	SZ

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Maximum	Brand Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

ADALIMUMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,

AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,

AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Note

Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

Note

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

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle,

AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle,

AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

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

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Maximum	Brand Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

Note

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

Note

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Maximum	Brand Name and Manufacturer
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agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialed it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Must be treated by a rheumatologist; OR							
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	No increase in the maximum number of repeats may be authorised.							
	Note							
	Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
9033K	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	3	..	1774.70	37.70	Humira	VE
9101B	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	3	..	1774.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

Note

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

Note

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

- (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping

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					Price for Max. Qty \$	Recordable Value for Safety Net \$	

therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

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Clinical criteria:								
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,								
AND								
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.								
Treatment criteria:								
Must be treated by a rheumatologist; OR								
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.								
Note								
No increase in the maximum quantity or number of units may be authorised.								
Note								
No increase in the maximum number of repeats may be authorised.								
Note								
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).								
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:								
Department of Human Services								
Prior Written Approval of Complex Drugs								
Reply Paid 9826								
GPO Box 9826								
HOBART TAS 7001								
9034L	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	5	..	1774.70	37.70	Humira	VE
9102C	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	5	..	1774.70	37.70	Humira	VE

CERTOLIZUMAB PEGOL

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,

AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,

AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,

AND

Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial

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	application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au) Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply. Authority required Severe psoriatic arthritis Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment) Clinical criteria: Patient must have a documented history of severe active psoriatic arthritis, AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. The authority application must be made in writing and must include: (1) a completed authority prescription form; and						

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(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

Note

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

Note

Special Pricing Arrangements apply.

Note

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

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

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Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in

GENERAL PHARMACEUTICAL BENEFITS

[illegible]

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Maximum	Brand Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 18 to 20 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 18 to 20 weeks treatment,

AND

The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note

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

Note

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

Note

Special Pricing Arrangements apply.

Note

Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:

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Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have been receiving treatment with certolizumab pegol for this condition prior to 1 April 2015,

AND

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Patient must be receiving treatment with certolizumab pegol at the time of application,

AND

Patient must have demonstrated a response to treatment as specified in the criteria for continuing PBS-subsidised treatment with certolizumab pegol,

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

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

Note

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

Note

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

Note

Special Pricing Arrangements apply.

Note

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

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Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they

GENERAL PHARMACEUTICAL BENEFITS

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	must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below]. The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle. Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment. Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle. Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime. How to prescribe biological agents for the treatment of severe active psoriatic arthritis. (1) Initial treatment. Applications for initial treatment should be made where: (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2). All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent. Grandfather patients - certolizumab pegol only. For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent. Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction. (2) Continuing treatment. Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent. (3) Swapping therapy. Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not. Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialed it on the PBS; and (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle. To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.						

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	(4) Baseline measurements to determine response.						
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.						
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.						
	(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.						
	Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.						
	<u>Authority required</u>						
	Severe psoriatic arthritis						
	Treatment Phase: Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) - balance of supply						
	Clinical criteria:						
	Patient must have received insufficient therapy with this drug under the Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment,						
	AND						
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.						
	Treatment criteria:						
	Must be treated by a rheumatologist; OR						
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.						
	<u>Note</u>						
	No increase in the maximum quantity or number of units may be authorised.						
	<u>Note</u>						
	No increase in the maximum number of repeats may be authorised.						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
	<u>Note</u>						
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	<u>Authority required</u>						
	Severe psoriatic arthritis						
	Treatment Phase: Continuing treatment						
	Clinical criteria:						
	Patient must have a documented history of severe active psoriatic arthritis,						
	AND						
	Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,						
	AND						
	Patient must demonstrate, at the time of application, an adequate response to treatment with this drug,						
	AND						
	Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis. Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.						

GENERAL PHARMACEUTICAL BENEFITS

[illegible]

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle. To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing. (4) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured. Authority required Severe psoriatic arthritis Treatment Phase: Continuing treatment - balance of supply Clinical criteria: Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply. Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
10238W	certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes	1	5	..	1708.98	37.70	Cimzia UC

DAPAGLIFLOZIN

Authority required (STREAMLINED)

4844

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

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

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

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

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

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

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

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

Note

Continuing Therapy Only:

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

Note

Dapagliflozin is not PBS subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

4825

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

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

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

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

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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(b) Had red cell transfusion within the previous 3 months.

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

Note

Continuing Therapy Only:

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

Note

Dapagliflozin is not PBS subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

10011X NP	dapagliflozin 10 mg tablet, 28	1	5	..	58.66	37.70	Forxiga	AP
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DESVENLAFAXINE

Restricted benefit

Major depressive disorders

Note

Continuing Therapy Only:

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

Note

Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

10231L NP	desvenlafaxine 100 mg tablet: modified release, 28 tablets	1	5	..	42.75	37.70	^a Desfax	AF
							^a Desvenlafaxine Actavis	GN
10234P NP	desvenlafaxine 50 mg tablet: modified release, 28 tablets	1	5	..	36.25	37.40	^a Desvenlafaxine GH XR	GQ
10241B NP	desvenlafaxine 50 mg tablet: modified release, 28 tablets	1	5	..	36.25	37.40	^a Desfax	AF
							^a Desvenlafaxine Actavis	GN
10245F NP	desvenlafaxine 100 mg tablet: modified release, 28 tablets	1	5	..	42.75	37.70	^a Desvenlafaxine GH XR	GQ
9366Y NP	desvenlafaxine 50 mg tablet: modified release, 28 tablets	1	5	..	36.25	37.40	^a Pristiq	PF
9367B NP	desvenlafaxine 100 mg tablet: modified release, 28 tablets	1	5	..	42.75	37.70	^a Pristiq	PF

EMPAGLIFLOZIN

Authority required (STREAMLINED)

4848

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

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

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

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Maximum	Brand Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

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

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

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

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

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

Note

Continuing Therapy Only:

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

Note

This drug is not PBS subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with an insulin, a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

10202Y NP	empagliflozin 25 mg tablet, 30	1	5	..	62.37	37.70	Jardiance	BY
10206E NP	empagliflozin 10 mg tablet, 30	1	5	..	62.37	37.70	Jardiance	BY

ETANERCEPT

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,

AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,

AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Note

Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

Note

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

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle,

AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle,

AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

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

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Maximum	Brand Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

Note

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

Note

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details

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[illegible]

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	(4) Baseline measurements to determine response.							
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.							
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.							
	(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.							
	Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.							
	<u>Authority required</u>							
	Severe psoriatic arthritis							
	Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply							
	Clinical criteria:							
	Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR							
	Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment,							
	AND							
	The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.							
	Treatment criteria:							
	Must be treated by a rheumatologist; OR							
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.							
	<u>Note</u>							
	No increase in the maximum quantity or number of units may be authorised.							
	<u>Note</u>							
	No increase in the maximum number of repeats may be authorised.							
	<u>Note</u>							
	Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
9035M	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	2	3	..	*1774.70	37.70	Enbrel	PF
9087G	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
9457R	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF

ETANERCEPT

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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	Patient must have a documented history of severe active psoriatic arthritis, AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						

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					Price for Max. Qty \$	Recordable Value for Safety Net \$	

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent

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	without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not. Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialed it on the PBS; and (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle. To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing. (4) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured. <u>Authority required</u> Severe psoriatic arthritis Treatment Phase: Continuing treatment - balance of supply Clinical criteria: Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
9036N	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	2	5	..	*1774.70	37.70	Enbrel	PF
9088H	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	5	..	1774.71	37.70	Enbrel	PF
9458T	ETANERCEPT Injection 50 mg in 1 mL	1	5	..	1774.71	37.70	Enbrel	PF

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	single use auto-injector, 4, 1							
EVEROLIMUS								
<u>Authority required</u>								
Stage IV clear cell variant renal cell carcinoma (RCC)								
Treatment Phase: Continuing treatment beyond 3 months								
Clinical criteria:								
Patient must have previously been issued with an authority prescription for this drug for this condition,								
AND								
Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),								
AND								
The treatment must be the sole PBS-subsidised therapy for this condition.								
Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.								
<u>Note</u>								
Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:								
Complete response (CR) is disappearance of all target lesions.								
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.								
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.								
Stable disease (SD) is small changes that do not meet above criteria.								
<u>Note</u>								
No increase in the maximum quantity or number of units may be authorised.								
<u>Note</u>								
No increase in the maximum number of repeats may be authorised.								
<u>Note</u>								
Special Pricing Arrangements apply.								
<u>Authority required</u>								
Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)								
Treatment Phase: Continuing treatment								
Clinical criteria:								
Patient must have previously been issued with an authority prescription for this drug,								
AND								
Patient must not have disease progression,								
AND								
The treatment must be as monotherapy.								
Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.								
<u>Note</u>								
No increase in the maximum quantity or number of units may be authorised.								
<u>Note</u>								
No increase in the maximum number of repeats may be authorised.								
<u>Note</u>								
Special Pricing Arrangements apply.								
10131F	everolimus 5 mg tablet, 30	1	5	..	2846.70	37.70	Afinitor	NV
10135K	everolimus 10 mg tablet, 30	1	5	..	5546.70	37.70	Afinitor	NV

EVEROLIMUS

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor,

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	AND							
	Patient must have a WHO performance status of 2 or less,							
	AND							
	The treatment must be the sole PBS-subsidised therapy for this condition.							
	Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.							
	Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.							
	Note							
	Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:							
	Complete response (CR) is disappearance of all target lesions.							
	Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.							
	Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.							
	Stable disease (SD) is small changes that do not meet above criteria.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	No increase in the maximum number of repeats may be authorised.							
	Note							
	Special Pricing Arrangements apply.							
	Authority required							
	Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)							
	Treatment Phase: Initial treatment							
	Clinical criteria:							
	Patient must be symptomatic (despite somatostatin analogues); OR							
	Patient must have disease progression,							
	AND							
	The treatment must be as monotherapy.							
	Disease progression must be documented in the patient's medical records.							
	Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus.							
	Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	No increase in the maximum number of repeats may be authorised.							
	Note							
	Special Pricing Arrangements apply.							
10132G	everolimus 10 mg tablet, 30	1	2	..	5546.70	37.70	Afinitor	NV
10133H	everolimus 5 mg tablet, 30	1	2	..	2846.70	37.70	Afinitor	NV

EXENATIDE

Authority required (STREAMLINED)

4856

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea,

AND

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Maximum	Brand Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

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

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

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

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

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

Note

This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), an insulin or an SGLT2 inhibitor.

Authority required (STREAMLINED)

4857

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin,

AND

The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

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

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

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

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

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

Note

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), an insulin or an SGLT2 inhibitor.								
3423E NP	exenatide 5 microgram/0.02 mL injection, 60 unit doses	1	5	..	70.34	37.70	Byetta 5 microgram	AP
3424F NP	exenatide 10 microgram/0.04 mL injection, 60 unit doses	1	5	..	97.60	37.70	Byetta 10 microgram	AP

FOLINIC ACID

Note

For item codes 8740B and 1610R, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.

1610R	folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules	1	2	..	58.56	37.70 ^a	Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF
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FOLINIC ACID

Note

For item codes 8740B and 1610R, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.

8740B	folinic acid 50 mg/5 mL injection, 1 x 5 mL vial	10	2	..	*58.56	37.70 ^a	Leucovorin Calcium (Hospira Pty Limited)	HH
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GOLIMUMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,

AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,

AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au) Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Authority required Severe psoriatic arthritis Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment) Clinical criteria: Patient must have a documented history of severe active psoriatic arthritis, AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND Patient must not receive more than 16 weeks of treatment under this restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug. Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.						

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

Note

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

Note

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.						
	Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.						
	There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.						
	How to prescribe biological agents for the treatment of severe active psoriatic arthritis.						
	(1) Initial treatment.						
	Applications for initial treatment should be made where:						
	(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and						
	(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and						
	(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).						
	All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.						
	Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.						
	Grandfather patients - certolizumab pegol only.						
	For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.						
	Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.						
	(2) Continuing treatment.						
	Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.						
	Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.						
	Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.						
	(3) Swapping therapy.						
	Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.						
	Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.						
	Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:						
	(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or						
	(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and						
	(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.						
	To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.						
	To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.						
	(4) Baseline measurements to determine response.						
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.						
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint						

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.							
	(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.							
	Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.							
	Authority required							
	Severe psoriatic arthritis							
	Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply							
	Clinical criteria:							
	Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR							
	Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment,							
	AND							
	The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.							
	Treatment criteria:							
	Must be treated by a rheumatologist; OR							
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	No increase in the maximum number of repeats may be authorised.							
	Note							
	Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
3430M	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	3	..	1777.63	37.70	Simponi	JC
3431N	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	3	..	1777.63	37.70	Simponi	JC

GOLIMUMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis. Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only. Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy. Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in						

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.							
	(4) Baseline measurements to determine response.							
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.							
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.							
	(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.							
	Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.							
	Authority required							
	Severe psoriatic arthritis							
	Treatment Phase: Continuing treatment - balance of supply							
	Clinical criteria:							
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,							
	AND							
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.							
	Treatment criteria:							
	Must be treated by a rheumatologist; OR							
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	No increase in the maximum number of repeats may be authorised.							
	Note							
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
3432P	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	5	..	1777.63	37.70	Simponi	JC
3433Q	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	5	..	1777.63	37.70	Simponi	JC
	IRON SUCROSE							
10229J NP	iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules	1	..	..	31.88	33.03	Venofer	AS
	IRON SUCROSE							
	Authority required (STREAMLINED)							
	4302							
	Iron deficiency anaemia							
	Treatment criteria:							
	Patient must be undergoing chronic haemodialysis.							
8807M	iron (as sucrose) 100 mg/5 mL	1	5	..	31.88	33.03	Venofer	AS

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
NP	injection, 5 x 5 mL ampoules						

LANTHANUM

Authority required (STREAMLINED)

4827

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

The treatment must not be used in combination with any other phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

Note

Shared Care Model:

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

9403X NP	LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90	1	5	..	306.22	37.70	Fosrenol	ZI
9404Y NP	LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90	1	5	..	449.77	37.70	Fosrenol	ZI
9405B NP	LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90	1	5	..	504.37	37.70	Fosrenol	ZI

MESALAZINE

Authority required (STREAMLINED)

4824

Ulcerative colitis

Clinical criteria:

Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR

Patient must be intolerant to sulfasalazine.

Note

Not for the treatment of Crohn disease

Note

Continuing Therapy Only:

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

10254Q NP	mesalazine 4 g granules: modified release, 30 sachets	1	5	..	312.64	37.70	Pentasa	FP
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SEVELAMER

Authority required (STREAMLINED)

4827

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

The treatment must not be used in combination with any other phosphate binding agents.

Treatment criteria:

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Patient must be undergoing dialysis for chronic kidney disease.							
	Note Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2142R NP	sevelamer hydrochloride 800 mg tablet, 180	1	5	..	358.07	37.70	Renagel	GZ
	SORAFENIB Authority required Stage IV clear cell variant renal cell carcinoma (RCC) Treatment Phase: Initial treatment Clinical criteria: Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, AND Patient must have a WHO performance status of 2 or less, AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.							
	Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows: Complete response (CR) is disappearance of all target lesions. Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions. Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions. Stable disease (SD) is small changes that do not meet above criteria.							
	Note No increase in the maximum quantity or number of units may be authorised.							
	Note No increase in the maximum number of repeats may be authorised.							
	Note Special Pricing Arrangements apply.							
10226F	sorafenib 200 mg tablet, 60	2	2	..	*6457.42	37.70	Nexavar	BN

SORAFENIB

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition,

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

AND

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

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Stable disease (SD) is small changes that do not meet above criteria.

Note

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

Note

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

Note

Special Pricing Arrangements apply.

10242C	sorafenib 200 mg tablet, 60	2	5	..	*6457.42	37.70	Nexavar	BN
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SUCROFERRIC OXYHYDROXIDE

Authority required (STREAMLINED)

4827

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

The treatment must not be used in combination with any other phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

Note

Shared Care Model:

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

10250L NP	iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90	1	5	..	429.82	37.70	Velphoro	FN
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SUNITINIB

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be symptomatic (despite somatostatin analogues); OR

Patient must have disease progression,

AND

The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition.

Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

Note

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

Note

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

Note

Special Pricing Arrangements apply.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
10004M	sunitinib 12.5 mg capsule, 28	1	2	..	1834.54	37.70	Sutent	PF
2837H	sunitinib 50 mg capsule, 28	1	2	..	6897.78	37.70	Sutent	PF
2959R	sunitinib 25 mg capsule, 28	1	2	..	3522.10	37.70	Sutent	PF

SUNITINIB

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug,

AND

Patient must not have disease progression,

AND

The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

Note

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

Note

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

Note

Special Pricing Arrangements apply.

10009T	sunitinib 12.5 mg capsule, 28	1	5	..	1834.54	37.70	Sutent	PF
10010W	sunitinib 50 mg capsule, 28	1	5	..	6897.78	37.70	Sutent	PF
2842N	sunitinib 25 mg capsule, 28	1	5	..	3522.10	37.70	Sutent	PF

VARENICLINE

Authority required

Nicotine dependence

Treatment Phase: Completion of a short-term (24 weeks) course of treatment

Clinical criteria:

The treatment must be as an aid to achieving abstinence from smoking,

AND

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

AND

Patient must have previously been issued with an authority prescription for this drug during this current course of treatment,

AND

Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.

Treatment criteria:

Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

Note

A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

Note

A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

Note

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

Note

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

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Maximum	Brand Name and Manufacturer	
					Price for Max. Qty \$	Recordable Value for Safety Net \$		
5469W NP	varenicline 1 mg tablet, 56	1	2	..	120.76	37.70	Champix	PF

HIGHLY SPECIALISED DRUGS PROGRAM (PUBLIC HOSPITAL)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for	Brand Name and Manufacturer	
					Max. Qty \$		
ALEMTUZUMAB							
<u>Authority required (STREAMLINED)</u>							
4834							
Multiple sclerosis							
Treatment Phase: Initial							
Clinical criteria:							
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR							
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,							
AND							
The treatment must be as monotherapy,							
AND							
Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years,							
AND							
Patient must be ambulatory (without assistance or support).							
Treatment criteria:							
Must be treated by a neurologist.							
Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.							
<u>Note</u>							
Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.							
<u>Note</u>							
Special Pricing Arrangements apply.							
<u>Note</u>							
No increase in the maximum quantity or number of units may be authorised.							
<u>Note</u>							
No increase in the maximum number of repeats may be authorised.							
10228H	alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial	5	..	..	*56970.00	Lemtrada	GZ

ALEMTUZUMAB

Authority required (STREAMLINED)

4829

Multiple sclerosis

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug,

AND

Patient must not show continuing progression of disability while on treatment with this drug,

AND

Patient must not receive more than one PBS-subsidised treatment per year,

AND

The treatment must be as monotherapy,

AND

Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

Must be treated by a neurologist.

Note

Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note

Special Pricing Arrangements apply.

Note

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
	No increase in the maximum quantity or number of units may be authorised.						
	Note						
	No increase in the maximum number of repeats may be authorised.						
10232M	alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial	3	..	..	*34182.00	Lemtrada	GZ
	APOMORPHINE						
	<u>Authority required (STREAMLINED)</u>						
	4833						
	Parkinson disease						
	Clinical criteria:						
	Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.						
10227G	apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules	72	5	..	*3596.40	Apomine	HH
5609F	apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules	72	5	..	*7196.40	Apomine	HH
5610G	apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules	36	5	..	*9003.60	Apomine	HH
5611H	apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes	36	5	..	*7007.40	Apomine PFS	HH
	DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE						
	<u>Authority required (STREAMLINED)</u>						
	4495						
	HIV infection						
	Treatment Phase: Initial						
	Clinical criteria:						
	Patient must be antiretroviral treatment naive.						
	Population criteria:						
	Patient must be aged 12 years or older,						
	AND						
	Patient must weigh 40 kg or more.						
	<u>Authority required (STREAMLINED)</u>						
	4480						
	HIV infection						
	Treatment Phase: Continuing						
	Clinical criteria:						
	Patient must have previously received PBS-subsidised therapy for HIV infection.						
	Population criteria:						
	Patient must be aged 12 years or older,						
	AND						
	Patient must weigh 40 kg or more.						
10247H	dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30	2	5	..	*2073.36	Triumeq	VI
	INFLIXIMAB						
	<u>Authority required</u>						
	Severe psoriatic arthritis						
	Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)						
	Clinical criteria:						
	Patient must have severe active psoriatic arthritis,						
	AND						
	Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR						
	Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,						

HIGHLY SPECIALISED DRUGS PROGRAM (PUBLIC HOSPITAL)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for	Brand Name and Manufacturer
					Max. Qty \$	
	AND					
	Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,					
	AND					
	Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR					
	Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,					
	AND					
	Patient must not receive more than 22 weeks of treatment under this restriction.					
	Population criteria:					
	Patient must be an adult.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.					
	For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.					
	Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.					
	Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.					
	The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:					
	an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either					
	(a) an active joint count of at least 20 active (swollen and tender) joints; or					
	(b) at least 4 active joints from the following list of major joints:					
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or					
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).					
	If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.					
	The authority application must be made in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and					
	(3) a signed patient acknowledgement.					
	At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.					
	<u>Note</u>					
	Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)					
	<u>Note</u>					
	The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.					
	<u>Note</u>					
	Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.					
	<u>Authority required</u>					
	Severe psoriatic arthritis					
	Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)					
	Clinical criteria:					
	Patient must have a documented history of severe active psoriatic arthritis,					
	AND					
	Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle,					
	AND					

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					for Max. Qty \$	
	Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle,					
	AND					
	Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle,					
	AND					
	Patient must not receive more than 22 weeks of treatment under this restriction.					
	Population criteria:					
	Patient must be an adult.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.					
	For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.					
	The authority application must be made in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.					
	At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.					
	Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.					
	Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.					
	Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.					
	Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.					
	An adequate response to treatment is defined as:					
	an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and					
	either of the following:					
	(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or					
	(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:					
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or					
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).					
	Note					
	The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.					
	Note					
	Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.					
	Note					
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au					
	Applications for authority to prescribe should be forwarded to:					
	Department of Human Services					
	Prior Written Approval of Complex Drugs					
	Reply Paid 9826					
	GPO Box 9826					
	HOBART TAS 7001					
	Note					

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					Max. Qty \$	

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents.

Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein

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					Max. Qty \$	

(CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment,

AND

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price	Brand Name and Manufacturer
					for Max. Qty \$	
	Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,					
	AND					
	Patient must demonstrate, at the time of application, an adequate response to treatment with this drug,					
	AND					
	Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.					
	Population criteria:					
	Patient must be an adult.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.					
	For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.					
	An adequate response to treatment is defined as:					
	an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and					
	either of the following:					
	(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or					
	(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:					
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or					
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).					
	The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.					
	All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.					
	Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.					
	The authority application must be made in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.					
	At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.					
	Note					
	Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.					
	Note					
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au					
	Applications for authority to prescribe should be forwarded to:					
	Department of Human Services					
	Prior Written Approval of Complex Drugs					
	Reply Paid 9826					
	GPO Box 9826					
	HOBART TAS 7001					
	Note					
	TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS					
	The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.					
	Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.					

HIGHLY SPECIALISED DRUGS PROGRAM (PUBLIC HOSPITAL)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for	Brand Name and Manufacturer
					Max. Qty \$	
	Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.					
	Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.					
	Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.					
	Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].					
	The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.					
	Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.					
	Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.					
	Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.					
	There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.					
	How to prescribe biological agents for the treatment of severe active psoriatic arthritis.					
	(1) Initial treatment.					
	Applications for initial treatment should be made where:					
	(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and					
	(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and					
	(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).					
	All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.					
	Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.					
	Grandfather patients - certolizumab pegol only.					
	For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.					
	Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.					
	(2) Continuing treatment.					
	Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.					
	Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.					
	(3) Swapping therapy.					
	Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.					
	Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.					
	Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:					

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for	Brand Name and Manufacturer
					Max. Qty \$	
	(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle. To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing. (4) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured. <u>Authority required</u> Severe psoriatic arthritis Treatment Phase: Continuing treatment - balance of supply Clinical criteria: Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001					
5756Y	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	751.70	Remicade

LANTHANUM

Authority required (STREAMLINED)

4832

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

JC

HIGHLY SPECIALISED DRUGS PROGRAM (PUBLIC HOSPITAL)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for	Brand Name and Manufacturer	
					Max. Qty \$		
The treatment must not be used in combination with any other phosphate binding agents.							
Treatment criteria:							
Patient must be undergoing dialysis for chronic kidney disease.							
5780F	LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90	2	5	..	*523.54	Fosrenol	ZI
5781G	LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90	2	5	..	*790.56	Fosrenol	ZI
5782H	LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90	2	5	..	*890.02	Fosrenol	ZI
SEVELAMER							
<u>Authority required (STREAMLINED)</u>							
4832							
Hyperphosphataemia							
Treatment Phase: Initiation and stabilisation							
Clinical criteria:							
The condition must not be adequately controlled by calcium,							
AND							
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR							
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,							
AND							
The treatment must not be used in combination with any other phosphate binding agents.							
Treatment criteria:							
Patient must be undergoing dialysis for chronic kidney disease.							
9546K	sevelamer hydrochloride 800 mg tablet, 180	2	5	..	*620.00	Renagel	GZ
SUCROFERRIC OXYHYDROXIDE							
<u>Authority required (STREAMLINED)</u>							
4832							
Hyperphosphataemia							
Treatment Phase: Initiation and stabilisation							
Clinical criteria:							
The condition must not be adequately controlled by calcium,							
AND							
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR							
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,							
AND							
The treatment must not be used in combination with any other phosphate binding agents.							
Treatment criteria:							
Patient must be undergoing dialysis for chronic kidney disease.							
10233N	iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90	2	5	..	*753.46	Velphoro	FN

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					for Max. Qty \$	
ALEMTUZUMAB						
<u>Authority required</u>						
Multiple sclerosis						
Treatment Phase: Initial						
Clinical criteria:						
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR						
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,						
AND						
The treatment must be as monotherapy,						
AND						
Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years,						
AND						
Patient must be ambulatory (without assistance or support).						
Treatment criteria:						
Must be treated by a neurologist.						
Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.						
<u>Note</u>						
Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.						
<u>Note</u>						
Special Pricing Arrangements apply.						
<u>Note</u>						
No increase in the maximum quantity or number of units may be authorised.						
<u>Note</u>						
No increase in the maximum number of repeats may be authorised.						
10243D	alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial	5	..	..	*57016.76	Lemtrada
						GZ

ALEMTUZUMAB
Authority required

Multiple sclerosis

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug,

AND

Patient must not show continuing progression of disability while on treatment with this drug,

AND

Patient must not receive more than one PBS-subsidised treatment per year,

AND

The treatment must be as monotherapy,

AND

Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

Must be treated by a neurologist.

Note

Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note

Special Pricing Arrangements apply.

Note

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

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND Patient must not receive more than 22 weeks of treatment under this restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised. Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au) Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Authority required Severe psoriatic arthritis Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment) Clinical criteria: Patient must have a documented history of severe active psoriatic arthritis, AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND					

HIGHLY SPECIALISED DRUGS PROGRAM (PRIVATE HOSPITAL)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price	Brand Name and Manufacturer
					for Max. Qty \$	
	Patient must not receive more than 22 weeks of treatment under this restriction.					
	Population criteria:					
	Patient must be an adult.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.					
	For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.					
	The authority application must be made in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.					
	At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.					
	Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.					
	Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.					
	Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.					
	Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.					
	An adequate response to treatment is defined as:					
	an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and					
	either of the following:					
	(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or					
	(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:					
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or					
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).					
	<u>Note</u>					
	The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.					
	<u>Note</u>					
	Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.					
	<u>Note</u>					
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au					
	Applications for authority to prescribe should be forwarded to:					
	Department of Human Services					
	Prior Written Approval of Complex Drugs					
	Reply Paid 9826					
	GPO Box 9826					
	HOBART TAS 7001					
	<u>Note</u>					
	TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS					
	The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.					
	Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.					

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for	Brand Name and Manufacturer
					Max. Qty \$	
	Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.					
	Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.					
	Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.					
	Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].					
	The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.					
	Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.					
	Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.					
	Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.					
	There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.					
	How to prescribe biological agents for the treatment of severe active psoriatic arthritis.					
	(1) Initial treatment.					
	Applications for initial treatment should be made where:					
	(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and					
	(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and					
	(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).					
	All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.					
	Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.					
	Grandfather patients - certolizumab pegol only.					
	For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.					
	Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.					
	(2) Continuing treatment.					
	Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.					
	Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.					
	(3) Swapping therapy.					
	Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.					
	Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.					
	Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:					

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for	Brand Name and Manufacturer
					Max. Qty \$	

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

- (4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

- (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment,

AND

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug,

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					Max. Qty \$	

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

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					Max. Qty \$	
	Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.					
	Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].					
	The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.					
	Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.					
	Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.					
	Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.					
	There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.					
	How to prescribe biological agents for the treatment of severe active psoriatic arthritis.					
	(1) Initial treatment.					
	Applications for initial treatment should be made where:					
	(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and					
	(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and					
	(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).					
	All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.					
	Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.					
	Grandfather patients - certolizumab pegol only.					
	For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.					
	Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.					
	(2) Continuing treatment.					
	Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.					
	Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.					
	(3) Swapping therapy.					
	Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.					
	Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.					
	Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:					
	(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or					
	(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and					
	(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.					
	To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					

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					for Max. Qty \$		
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing. (4) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured. <u>Authority required</u> Severe psoriatic arthritis Treatment Phase: Continuing treatment - balance of supply Clinical criteria: Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
6496X	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	788.53	Remicade	JC
LANTHANUM <u>Authority required</u> Hyperphosphataemia Treatment Phase: Initiation and stabilisation Clinical criteria: The condition must not be adequately controlled by calcium, AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND The treatment must not be used in combination with any other phosphate binding agents. Treatment criteria: Patient must be undergoing dialysis for chronic kidney disease.							
9635D	LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90	2	5	..	*551.24	Fosrenol	ZI
9636E	LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90	2	5	..	*828.94	Fosrenol	ZI

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					Max. Qty \$		
9637F	LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90	2	5	..	*932.38	Fosrenol	ZI
SEVELAMER <u>Authority required</u> Hyperphosphataemia Treatment Phase: Initiation and stabilisation Clinical criteria: The condition must not be adequately controlled by calcium, AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND The treatment must not be used in combination with any other phosphate binding agents. Treatment criteria: Patient must be undergoing dialysis for chronic kidney disease.							
9620H	sevelamer hydrochloride 800 mg tablet, 180	2	5	..	*651.56	Renagel	GZ
SUCROFERRIC OXYHYDROXIDE <u>Authority required</u> Hyperphosphataemia Treatment Phase: Initiation and stabilisation Clinical criteria: The condition must not be adequately controlled by calcium, AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND The treatment must not be used in combination with any other phosphate binding agents. Treatment criteria: Patient must be undergoing dialysis for chronic kidney disease.							
10230K	iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90	2	5	..	*790.36	Velphoro	FN

SECTION 100 – BOTULINUM TOXIN PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	BOTULINUM TOXIN TYPE A <u>Restricted benefit</u> Blepharospasm or hemifacial spasm Population criteria: Patient must be aged 12 years or older. <u>Note</u> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. <u>Note</u> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. <u>Restricted benefit</u> Dynamic equinus foot deformity Clinical criteria: The condition must be due to spasticity, AND Patient must be an ambulant cerebral palsy patient. Population criteria: Patient must be aged from 2 to 17 years inclusive. <u>Note</u> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. <u>Note</u> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. <u>Restricted benefit</u> Dynamic equinus foot deformity Clinical criteria: The condition must be due to spasticity, AND Patient must be an ambulant cerebral palsy patient, AND Patient must have commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient. Population criteria: Patient must be aged 18 years or older. <u>Note</u> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. <u>Note</u> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. <u>Restricted benefit</u> Spasmodic torticollis Clinical criteria: The treatment must be as monotherapy; OR The treatment must be as adjunctive therapy to current standard care. <u>Note</u> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. <u>Note</u> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. <u>Restricted benefit</u> Moderate to severe spasticity of the upper limb Clinical criteria: Patient must have cerebral palsy.						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Population criteria: Patient must be aged from 2 to 17 years inclusive. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Restricted benefit Moderate to severe spasticity of the upper limb Clinical criteria: Patient must have cerebral palsy, AND Patient must have commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient. Population criteria: Patient must be aged 18 years or older. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note Contact the Department of Human Services before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Restricted benefit Moderate to severe spasticity of the upper limb following a stroke Clinical criteria: The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy. Population criteria: Patient must be an adult. Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale. Maximum number of treatments to be authorised is 4 (total Xeomin®, Botox® and Dysport®) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments. The date of the stroke must be provided. Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Restricted benefit Severe primary axillary hyperhidrosis Clinical criteria: Patient must have previously failed or be intolerant to topical aluminium chloride hexahydrate after one to two months of treatment. Population criteria: Patient must be aged 12 years or older. Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Note						

SECTION 100 – BOTULINUM TOXIN PROGRAM

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	Special Pricing Arrangements apply.						
	<u>Restricted benefit</u>						
	Urinary incontinence						
	Clinical criteria:						
	The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study,						
	AND						
	The condition must be inadequately controlled by anti-cholinergic therapy,						
	AND						
	Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin,						
	AND						
	The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment,						
	AND						
	Patient must be willing and able to self-catheterise.						
	Population criteria:						
	Patient must have multiple sclerosis; OR						
	Patient must have a spinal cord injury; OR						
	Patient must be aged 18 years or older and have spina bifida.						
	<u>Note</u>						
	Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.						
	<u>Note</u>						
	The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
	<u>Restricted benefit</u>						
	Chronic migraine						
	Clinical criteria:						
	Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin,						
	AND						
	Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin,						
	AND						
	Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment.						
	Population criteria:						
	Patient must be an adult.						
	Medication overuse headache must be appropriately managed prior to initiation of treatment with botulinum toxin.						
	<u>Note</u>						
	Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.						
	<u>Note</u>						
	The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
	<u>Restricted benefit</u>						
	Urinary incontinence						
	Clinical criteria:						
	The condition must be due to idiopathic overactive bladder,						
	AND						
	The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents.						

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	AND							
	Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin,							
	AND							
	The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment,							
	AND							
	Patient must be willing and able to self-catheterise.							
	Population criteria:							
	Patient must be aged 18 years or older.							
	Note							
	Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.							
	Note							
	The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.							
	Note							
	Special Pricing Arrangements apply.							
6103F	botulinum toxin type A 100 units injection, 1 x 100 units vial	1	..	..	415.50	NaN	Botox	AG

CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Restricted benefit

Moderate to severe spasticity of the upper limb following a stroke

Clinical criteria:

The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

Population criteria:

Patient must be an adult.

Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale.

Maximum number of treatments to be authorised is 4 (total Xeomin®, Botox® and Dysport®) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.

The date of the stroke must be provided.

Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin.

Note

Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

Note

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Restricted benefit

Dynamic equinus foot deformity

Clinical criteria:

The condition must be due to spasticity,

AND

Patient must be an ambulant cerebral palsy patient.

Population criteria:

Patient must be aged from 2 to 17 years inclusive.

Note

Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

Note

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Restricted benefit

Dynamic equinus foot deformity

Clinical criteria:

SECTION 100 – BOTULINUM TOXIN PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	The condition must be due to spasticity, AND Patient must be an ambulant cerebral palsy patient, AND Patient must have commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient. Population criteria: Patient must be aged 18 years or older. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Restricted benefit Spasmodic torticollis Clinical criteria: The treatment must be as monotherapy; OR The treatment must be as adjunctive therapy to current standard care. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Restricted benefit Blepharospasm or hemifacial spasm Population criteria: Patient must be an adult. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.						
1152P	clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 x 300 units vial	1	..	..	361.52	NaN	Dysport IS
6293F	clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 x 500 units vial	1	..	..	644.81	NaN	Dysport IS
	INCOBOTULINUMTOXINA Restricted benefit Spasmodic torticollis Clinical criteria: The treatment must be as monotherapy; OR The treatment must be as adjunctive therapy to current standard care. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Restricted benefit Blepharospasm Population criteria: Patient must be an adult. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number						

SECTION 100 – BOTULINUM TOXIN PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	1800 700 270.							
	<u>Note</u> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. <u>Restricted benefit</u> Moderate to severe spasticity of the upper limb following a stroke <u>Clinical criteria:</u> The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy. <u>Population criteria:</u> Patient must be an adult. Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale. Maximum number of treatments to be authorised is 4 (total Xeomin®, Botox® and Dysport®) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments. The date of the stroke must be provided. Contraindications to treatment include established severe contracture and known sensitivity to botulinum neurotoxin. <u>Note</u> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. <u>Note</u> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.							
10253P	incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial	1	..	..	375.00	NaN	Xeomin	EZ

