



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

General Pharmaceutical Schedule - Volume 1

Effective 1 September 2019

This Schedule is also available at www.pbs.gov.au



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

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Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 September 2019 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$7.39
	Dangerous drug fee	\$3.11
	Extemporaneously-prepared	\$9.43
	Allowable additional patient charge*	\$4.53
Additional Fees (for safety net prices):	Ready-prepared	\$1.25
	Extemporaneously-prepared	\$1.61
Patient Co-payments:	General	\$40.30
	Concessional	\$6.50
Safety Net Thresholds:	General	\$1550.70
	Concessional	\$390.00
Safety Net Card Issue Fee:		\$10.10

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

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 September 2019. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Additions

Addition – Item

11755Q **BENZATHINE BENZYL PENICILLIN**, benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes (*Bicillin L-A*)

Addition – Brand

3479D **MORPHINE SULFATE 15 mg/1 mL MEDSURGE, DZ – MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

3480E **MORPHINE SULFATE 30 mg/1 mL MEDSURGE, DZ – MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

Addition – Equivalence Indicator

3479D *Hospira Pty Limited, PF – MORPHINE*, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

3480E *Hospira Pty Limited, PF – MORPHINE*, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

General Pharmaceutical Benefits

Additions

Addition – Item

11757T **IMATINIB**, imatinib 100 mg capsule, 60 (*CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX*)

11770L **IMATINIB**, imatinib 100 mg capsule, 60 (*CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX*)

11776T **IMATINIB**, imatinib 100 mg capsule, 60 (*CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX*)

11777W **IMATINIB**, imatinib 100 mg capsule, 60 (*CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX*)

11782D **IMATINIB**, imatinib 100 mg capsule, 60 (*CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX*)

11783E **IMATINIB**, imatinib 100 mg capsule, 60 (*CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX*)

11756R **IMATINIB**, imatinib 400 mg capsule, 30 (*CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX*)

11763D **IMATINIB**, imatinib 400 mg capsule, 30 (*CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX*)

11764E **IMATINIB**, imatinib 400 mg capsule, 30 (*CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX*)

11771M **IMATINIB**, imatinib 400 mg capsule, 30 (*CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX*)

11772N	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
11779Y	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
11753N	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
11762C	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec, IMATINIB RBX</i>)
11769K	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
11775R	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
11780B	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
11781C	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
11784F	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i>)
11787J	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i>)
11752M	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
11758W	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
11765F	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
11778X	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i>)
11785G	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec, IMATINIB RBX</i>)
11786H	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
11788K	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i>)
11789L	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)

Addition – Brand

1088G	<i>APO-Flecainide, TX</i> – FLECAINIDE , flecainide acetate 50 mg tablet, 60
1090J	<i>APO-Flecainide, TX</i> – FLECAINIDE , flecainide acetate 100 mg tablet, 60
1644M	<i>MORPHINE SULFATE 10 mg/1 mL MEDSURGE, DZ</i> – MORPHINE , morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules
5168B	<i>MORPHINE SULFATE 10 mg/1 mL MEDSURGE, DZ</i> – MORPHINE , morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules
1645N	<i>MORPHINE SULFATE 15 mg/1 mL MEDSURGE, DZ</i> – MORPHINE , morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules
5169C	<i>MORPHINE SULFATE 15 mg/1 mL MEDSURGE, DZ</i> – MORPHINE , morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules
1647Q	<i>MORPHINE SULFATE 30 mg/1 mL MEDSURGE, DZ</i> – MORPHINE , morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules
5170D	<i>MORPHINE SULFATE 30 mg/1 mL MEDSURGE, DZ</i> – MORPHINE , morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules
5292M	<i>OLMEKAR, RW</i> – OLMESARTAN MEDOXOMIL + AMLODIPINE , olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30
5293N	<i>OLMEKAR, RW</i> – OLMESARTAN MEDOXOMIL + AMLODIPINE , olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30
5294P	<i>OLMEKAR, RW</i> – OLMESARTAN MEDOXOMIL + AMLODIPINE , olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30
2898M	<i>TERIFLAGIO, RW</i> – TERIFLUNOMIDE , teriflunomide 14 mg tablet, 28

Addition – Equivalence Indicator

11726E	<i>Cal-500, PP</i> – CALCIUM , CALCIUM Tablet (chewable) 500 mg (as carbonate), 120
3116B	<i>Cal-500, PP</i> – CALCIUM , CALCIUM Tablet (chewable) 500 mg (as carbonate), 60
1645N	<i>Hospira Pty Limited, PF</i> – MORPHINE , morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules
5169C	<i>Hospira Pty Limited, PF</i> – MORPHINE , morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules
1647Q	<i>Hospira Pty Limited, PF</i> – MORPHINE , morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

5170D Hospira Pty Limited, PF – **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

Addition – Note

11726E **CALCIUM**, CALCIUM Tablet (chewable) 500 mg (as carbonate), 120 (*Cal-500*)

3116B **CALCIUM**, CALCIUM Tablet (chewable) 500 mg (as carbonate), 60 (*Cal-500*)

Deletions

Deletion – Item

1923F **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE**, amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid, 30 x 130 mL pouches (*MMA/PA cooler 15*)

1280J **HYDROCHLOROTHIAZIDE + TRIAMTERENE**, hydrochlorothiazide 25 mg + triamterene 50 mg tablet, 100 (*Hydrene 25/50*)

1711C **INSULIN ISOPHANE BOVINE**, insulin isophane bovine 100 units/mL injection, 1 x 10 mL vial (*Hypurin Isophane*)

1713E **INSULIN NEUTRAL BOVINE**, insulin neutral bovine 100 units/mL injection, 1 x 10 mL vial (*Hypurin Neutral*)

2373X **MACROGOL-3350**, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets (*Herron ClearLax*)

2034C **PAZOPANIB**, pazopanib 200 mg tablet, 90 (*Votrient*)

2035D **PAZOPANIB**, pazopanib 400 mg tablet, 60 (*Votrient*)

10928E **RIBAVIRIN**, ribavirin 200 mg tablet, 28 (*Ibavyr*)

10937P **RIBAVIRIN**, ribavirin 200 mg tablet, 28 (*Ibavyr*)

10143W **SALBUTAMOL**, salbutamol 200 microgram powder for inhalation, 128 capsules (*Ventolin Rotacaps*)

Deletion – Brand

9351E *Fosamax Plus D-Cal, MK* – **ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE**, alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack

10103R *Exaccord, RA* – **EXEMESTANE**, exemestane 25 mg tablet, 30

8506Q *Exaccord, RA* – **EXEMESTANE**, exemestane 25 mg tablet, 30

8217L *Famciclovir FBM, FO* – **FAMCICLOVIR**, famciclovir 250 mg tablet, 56

2436F *Indapamide Sandoz, SZ* – **INDAPAMIDE**, indapamide hemihydrate 2.5 mg tablet, 90

8855C *Avanza SolTab, MK* – **MIRTAZAPINE**, mirtazapine 15 mg orally disintegrating tablet, 30

8856D *Avanza SolTab, MK* – **MIRTAZAPINE**, mirtazapine 30 mg orally disintegrating tablet, 30

8857E *Avanza SolTab, MK* – **MIRTAZAPINE**, mirtazapine 45 mg orally disintegrating tablet, 30

2834E *Cholvastin, RA* – **PRAVASTATIN**, pravastatin sodium 20 mg tablet, 30

9238F *Cholvastin, RA* – **PRAVASTATIN**, pravastatin sodium 20 mg tablet, 30

8197K *Cholvastin, RA* – **PRAVASTATIN**, pravastatin sodium 40 mg tablet, 30

9239G *Cholvastin, RA* – **PRAVASTATIN**, pravastatin sodium 40 mg tablet, 30

1316G *Chem mart Ramipril, CH* – **RAMIPRIL**, ramipril 10 mg tablet, 30

1316G *Terry White Chemists Ramipril, TW* – **RAMIPRIL**, ramipril 10 mg tablet, 30

9391G *ATELVIA ONCE-A-MONTH, TU* – **RISEDRONATE**, risedronate sodium 150 mg tablet, 1

Deletion – Equivalence Indicator

3416T *OsmoLax, KY* – **MACROGOL-3350**, macrogol-3350 1 g/g powder for oral liquid, 510 g

Deletion – Note

3416T **MACROGOL-3350**, macrogol-3350 1 g/g powder for oral liquid, 510 g (*OsmoLax*)

Alterations

Alteration – Item Description

From

8526R **TENECTEPLASE**, tenecteplase 8000 units (40 mg) injection [1 vial] (&) inert substance diluent [8 mL syringe], 1 pack (*Metalyse*)

To	
8526R	TENECTEPLASE , tenecteplase 40 mg injection [1 vial] (&) inert substance diluent [8 mL syringe], 1 pack (Metalyse)
From	
8527T	TENECTEPLASE , tenecteplase 10 000 units (50 mg) injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack (Metalyse)
To	
8527T	TENECTEPLASE , tenecteplase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack (Metalyse)

Alteration – Note

1354G	DASATINIB , dasatinib 20 mg tablet, 60 (<i>Sprycel</i>)
1381Q	DASATINIB , dasatinib 50 mg tablet, 60 (<i>Sprycel</i>)
1415L	DASATINIB , dasatinib 70 mg tablet, 60 (<i>Sprycel</i>)
1416M	DASATINIB , dasatinib 100 mg tablet, 30 (<i>Sprycel</i>)
10915L	IMATINIB , imatinib 100 mg capsule, 60 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10918P	IMATINIB , imatinib 100 mg capsule, 60 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10924Y	IMATINIB , imatinib 100 mg capsule, 60 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10940T	IMATINIB , imatinib 100 mg capsule, 60 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10941W	IMATINIB , imatinib 100 mg capsule, 60 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10942X	IMATINIB , imatinib 100 mg capsule, 60 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10916M	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10917N	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10921T	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10925B	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10933K	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10939R	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
5443L	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i>)
9111M	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i>)
9113P	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9123E	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9172R	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9174W	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9176Y	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9178C	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec, IMATINIB RBX</i>)
5444M	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i>)
9112N	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i>)
9114Q	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9124F	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9173T	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9175X	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)

9177B	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9179D	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec, IMATINIB RBX</i>)
Alteration – Restriction	
1354G	DASATINIB , dasatinib 20 mg tablet, 60 (<i>Sprycel</i>)
1381Q	DASATINIB , dasatinib 50 mg tablet, 60 (<i>Sprycel</i>)
1415L	DASATINIB , dasatinib 70 mg tablet, 60 (<i>Sprycel</i>)
1416M	DASATINIB , dasatinib 100 mg tablet, 30 (<i>Sprycel</i>)
10915L	IMATINIB , imatinib 100 mg capsule, 60 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10918P	IMATINIB , imatinib 100 mg capsule, 60 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10924Y	IMATINIB , imatinib 100 mg capsule, 60 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10940T	IMATINIB , imatinib 100 mg capsule, 60 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10941W	IMATINIB , imatinib 100 mg capsule, 60 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10942X	IMATINIB , imatinib 100 mg capsule, 60 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10916M	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10917N	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10921T	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10925B	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10933K	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
10939R	IMATINIB , imatinib 400 mg capsule, 30 (<i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
5443L	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i>)
9111M	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i>)
9113P	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9123E	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9172R	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9174W	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9176Y	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9178C	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec, IMATINIB RBX</i>)
5444M	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i>)
9112N	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i>)
9114Q	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9124F	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9173T	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9175X	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9177B	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9179D	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec, IMATINIB RBX</i>)
10042M	PAZOPANIB , pazopanib 200 mg tablet, 90 (<i>Votrient</i>)

2029T	PAZOPANIB , pazopanib 200 mg tablet, 90 (<i>Votrient</i>)
10041L	PAZOPANIB , pazopanib 400 mg tablet, 60 (<i>Votrient</i>)
2030W	PAZOPANIB , pazopanib 400 mg tablet, 60 (<i>Votrient</i>)
9417P	SUNITINIB , sunitinib 12.5 mg capsule, 28 (<i>Sutent</i>)
9418Q	SUNITINIB , sunitinib 25 mg capsule, 28 (<i>Sutent</i>)
10504W	SUNITINIB , sunitinib 37.5 mg capsule, 28 (<i>Sutent</i>)
9419R	SUNITINIB , sunitinib 50 mg capsule, 28 (<i>Sutent</i>)

Alteration – Restriction Level

		<i>From</i>	<i>To</i>
10042M	PAZOPANIB , pazopanib 200 mg tablet, 90 (<i>Votrient</i>)	authority-required	streamlined
2029T	PAZOPANIB , pazopanib 200 mg tablet, 90 (<i>Votrient</i>)	authority-required	streamlined
10041L	PAZOPANIB , pazopanib 400 mg tablet, 60 (<i>Votrient</i>)	authority-required	streamlined
2030W	PAZOPANIB , pazopanib 400 mg tablet, 60 (<i>Votrient</i>)	authority-required	streamlined
9417P	SUNITINIB , sunitinib 12.5 mg capsule, 28 (<i>Sutent</i>)	authority-required	streamlined
9418Q	SUNITINIB , sunitinib 25 mg capsule, 28 (<i>Sutent</i>)	authority-required	streamlined
10504W	SUNITINIB , sunitinib 37.5 mg capsule, 28 (<i>Sutent</i>)	authority-required	streamlined
9419R	SUNITINIB , sunitinib 50 mg capsule, 28 (<i>Sutent</i>)	authority-required	streamlined

Advance Notices

1 October 2019

Deletion – Brand

2544X	<i>Akineton</i> , GH – BIPERIDEN , biperiden hydrochloride 2 mg tablet, 100
8315P	<i>DBL Cefepime</i> , PF – CEFEPIME , cefepime 1 g injection, 1 vial
8316Q	<i>DBL Cefepime</i> , PF – CEFEPIME , cefepime 2 g injection, 1 vial
8246B	<i>Irprestan 75</i> , ZP – IRBESARTAN , irbesartan 75 mg tablet, 30
8247C	<i>Irprestan 150</i> , ZP – IRBESARTAN , irbesartan 150 mg tablet, 30
8248D	<i>Irprestan 300</i> , ZP – IRBESARTAN , irbesartan 300 mg tablet, 30
1594X	<i>Onsetron 4</i> , ZP – ONDANSETRON , ondansetron 4 mg tablet, 10
1595Y	<i>Onsetron 8</i> , ZP – ONDANSETRON , ondansetron 8 mg tablet, 10
1596B	<i>Onsetron</i> , ZP – ONDANSETRON , ondansetron 4 mg/2 mL injection, 2 mL ampoule
1597C	<i>Onsetron</i> , ZP – ONDANSETRON , ondansetron 8 mg/4 mL injection, 4 mL ampoule
8224W	<i>Onsetron 4</i> , ZP – ONDANSETRON , ondansetron 4 mg tablet, 4
8225X	<i>Onsetron 8</i> , ZP – ONDANSETRON , ondansetron 8 mg tablet, 4
8226Y	<i>Onsetron</i> , ZP – ONDANSETRON , ondansetron 4 mg/2 mL injection, 2 mL ampoule
8227B	<i>Onsetron</i> , ZP – ONDANSETRON , ondansetron 8 mg/4 mL injection, 4 mL ampoule
8507R	<i>Parzol 10</i> , ZP – RABEPRAZOLE , rabeprazole sodium 10 mg enteric tablet, 28
8508T	<i>Parzol 20</i> , ZP – RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30
8509W	<i>Parzol 20</i> , ZP – RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30
10538P	<i>Rivastigmelon Patch 15</i> , AF – RIVASTIGMINE , rivastigmine 13.3 mg/24 hours patch, 30
10541T	<i>Rivastigmelon Patch 15</i> , AF – RIVASTIGMINE , rivastigmine 13.3 mg/24 hours patch, 30
2477J	<i>Rivastigmelon Patch 5</i> , AF – RIVASTIGMINE , rivastigmine 4.6 mg/24 hours patch, 30
2551G	<i>Rivastigmelon Patch 10</i> , AF – RIVASTIGMINE , rivastigmine 9.5 mg/24 hours patch, 30
9161E	<i>Rivastigmelon Patch 5</i> , AF – RIVASTIGMINE , rivastigmine 4.6 mg/24 hours patch, 30
9162F	<i>Rivastigmelon Patch 10</i> , AF – RIVASTIGMINE , rivastigmine 9.5 mg/24 hours patch, 30
2018F	<i>Myocrisin</i> , SW – SODIUM AUROTHIOMALATE , sodium aurothiomalate 50 mg/0.5 mL injection, 10 x 0.5 mL ampoules

5299X	<i>Prograf XL, LL</i> – TACROLIMUS , tacrolimus 500 microgram modified release capsule, 30
5300Y	<i>Prograf XL, LL</i> – TACROLIMUS , tacrolimus 1 mg modified release capsule, 60
5451X	<i>Prograf XL, LL</i> – TACROLIMUS , tacrolimus 5 mg modified release capsule, 30
1925H	<i>Timoptol XE, MF</i> – TIMOLOL , timolol 0.25% eye drops, 2.5 mL
5549C	<i>Timoptol XE, MF</i> – TIMOLOL , timolol 0.25% eye drops, 2.5 mL
8523N	<i>Lodam SR 100, ZP</i> – TRAMADOL , tramadol hydrochloride 100 mg modified release tablet, 20
8524P	<i>Lodam SR 150, ZP</i> – TRAMADOL , tramadol hydrochloride 150 mg modified release tablet, 20

1 November 2019

Deletion – Brand

3116B	<i>Cal-500, PP</i> – CALCIUM , CALCIUM Tablet (chewable) 500 mg (as carbonate), 60
11438B	<i>Carbzero, VF</i> – LONG CHAIN TRIGLYCERIDES , long chain triglycerides oral liquid, 15 x 225 mL bottles

1 December 2019

Deletion – Brand

1002R	<i>Zovirax, GK</i> – ACICLOVIR , aciclovir 3% eye ointment, 4.5 g
5501M	<i>Zovirax, GK</i> – ACICLOVIR , aciclovir 3% eye ointment, 4.5 g
10784N	<i>Bactrim DS, RO</i> – TRIMETHOPRIM + SULFAMETHOXAZOLE , trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10
2951H	<i>Bactrim DS, RO</i> – TRIMETHOPRIM + SULFAMETHOXAZOLE , trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10
3390K	<i>Bactrim DS, RO</i> – TRIMETHOPRIM + SULFAMETHOXAZOLE , trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

1 January 2020

Deletion – Brand

8362D	<i>Capecitabine Apotex, TX</i> – CAPECITABINE , capecitabine 500 mg tablet, 120

Palliative Care

Additions

Addition – Item

11760Y	MORPHINE , morphine sulfate pentahydrate 10 mg modified release capsule, 28 (<i>Kapanol</i>)
11761B	MORPHINE , morphine sulfate pentahydrate 20 mg modified release capsule, 28 (<i>Kapanol</i>)

Deletions

Deletion – Item

2351R	MACROGOL-3350 , macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets (<i>Herron ClearLax</i>)

Deletion – Equivalence Indicator

5426N	<i>OsmoLax, KY</i> – MACROGOL-3350 , macrogol-3350 1 g/g powder for oral liquid, 510 g

Deletion – Note

5426N	MACROGOL-3350 , macrogol-3350 1 g/g powder for oral liquid, 510 g (<i>OsmoLax</i>)

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Brand

6100C	<i>Azacitidine Juno, JO</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
6138C	<i>Azacitidine Juno, JO</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial

Deletions

Deletion – Item

10923X	RIBAVIRIN , ribavirin 200 mg tablet, 28 (<i>Ibavyr</i>)
10938Q	RIBAVIRIN , ribavirin 200 mg tablet, 28 (<i>Ibavyr</i>)

10554L **ZOLEDRONIC ACID**, zoledronic acid 4 mg/100 mL injection, 100 mL vial (*Zoledronic Acid 4 mg/100 mL APOTEX*)

Alterations

Alteration – Item Description

From
9574X **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe (*Mircera*)

To
9574X **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 0.3 mL syringe (*Mircera*)

From
9575Y **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe (*Mircera*)

To
9575Y **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 0.3 mL syringe (*Mircera*)

From
9576B **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe (*Mircera*)

To
9576B **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 0.3 mL syringe (*Mircera*)

From
9577C **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe (*Mircera*)

To
9577C **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 0.3 mL syringe (*Mircera*)

From
9578D **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe (*Mircera*)

To
9578D **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 0.3 mL syringe (*Mircera*)

From
9579E **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe (*Mircera*)

To
9579E **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 0.3 mL syringe (*Mircera*)

From
9580F **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe (*Mircera*)

To
9580F **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**, methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 0.6 mL syringe (*Mircera*)

Alteration – Restriction

11548T **DEFERASIROX**, deferasirox 90 mg tablet, 30 (*Jadenu*)

11510T **DEFERASIROX**, deferasirox 180 mg tablet, 30 (*Jadenu*)

11547R **DEFERASIROX**, deferasirox 360 mg tablet, 30 (*Jadenu*)

9638G **DEFERIPRONE**, deferiprone 100 mg/mL oral liquid, 250 mL (*Ferriprox*)

6416Q **DEFERIPRONE**, deferiprone 500 mg tablet, 100 (*Ferriprox*)

6249X **DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)**, doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial (*Caelyx, Liposomal Doxorubicin SUN*)

9619G **IBANDRONATE**, ibandronate 6 mg/6 mL injection, 6 mL vial (*Bondronat*)

6210W **INTERFERON ALFA-2A**, interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe (*Roferon-A*)

6213B **INTERFERON ALFA-2A**, interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe (*Roferon-A*)

6423C **LANREOTIDE**, lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe (*Somatuline Autogel*)

6424D	LANREOTIDE , lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe (<i>Somatuline Autogel</i>)
11527Q	LANREOTIDE , lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe (<i>Somatuline Autogel</i>)
6425E	LANREOTIDE , lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe (<i>Somatuline Autogel</i>)
6332G	LANREOTIDE , lanreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack (<i>Somatuline LA</i>)
11517E	LENOGRASTIM , lenograstim 13.4 million units (105 microgram) injection, 1 vial (<i>Granocyte 13</i>)
11530W	LENOGRASTIM , lenograstim 33.6 million units (263 microgram) injection, 1 vial (<i>Granocyte 34</i>)
10931H	LIPEGFILGRASTIM , lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (<i>Lonquex</i>)
6227R	OCTREOTIDE , octreotide 50 microgram/mL injection, 5 x 1 mL ampoules (<i>Hospira Pty Limited, Octreotide (SUN), Octreotide MaxRx, Sandostatin 0.05</i>)
6228T	OCTREOTIDE , octreotide 100 microgram/mL injection, 5 x 1 mL ampoules (<i>Hospira Pty Limited, Octreotide (SUN), Octreotide MaxRx, Sandostatin 0.1</i>)
6229W	OCTREOTIDE , octreotide 500 microgram/mL injection, 5 x 1 mL ampoules (<i>Hospira Pty Limited, Octreotide (SUN), Octreotide MaxRx, Sandostatin 0.5</i>)
10566D	OCTREOTIDE , octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
10549F	OCTREOTIDE , octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
10558Q	OCTREOTIDE , octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
6286W	PAMIDRONATE DISODIUM , pamidronate disodium 15 mg/5 mL injection, 5 mL vial (<i>Pamisol</i>)
6287X	PAMIDRONATE DISODIUM , pamidronate disodium 30 mg/10 mL injection, 10 mL vial (<i>Pamisol</i>)
6288Y	PAMIDRONATE DISODIUM , pamidronate disodium 60 mg/10 mL injection, 10 mL vial (<i>Pamisol</i>)
6289B	PAMIDRONATE DISODIUM , pamidronate disodium 90 mg/10 mL injection, 10 mL vial (<i>Pamisol</i>)
6363X	PEGFILGRASTIM , pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (<i>Neulasta, Ristempa, Tezmota</i>)
10084R	PLERIXAFOR , plerixafor 24 mg/1.2 mL injection, 1.2 mL vial (<i>Mozobil</i>)
6469L	THALIDOMIDE , thalidomide 50 mg capsule, 28 (<i>Thalomid</i>)
9684Q	THALIDOMIDE , thalidomide 100 mg capsule, 28 (<i>Thalomid</i>)
6280M	VALACICLOVIR , valaciclovir 500 mg tablet, 100 (<i>APO-Valaciclovir, Valaciclovir APOTEX, Valaciclovir RBX, Valtrex</i>)
9675F	VALGANCICLOVIR , valganciclovir 50 mg/mL powder for oral liquid, 100 mL (<i>Valcyte</i>)
6357N	VALGANCICLOVIR , valganciclovir 450 mg tablet, 60 (<i>Valcyte, Valganciclovir AN, Valganciclovir Juno, Valganciclovir Mylan, Valganciclovir Sandoz</i>)
11405G	ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 5 x 5 mL vials (<i>Clarix Lifesciences Zoledronic Acid</i>)
6371H	ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 5 mL vial (<i>APO-Zoledronic Acid, DBL Zoledronic Acid, DEZTRON, Zometa</i>)
10542W	ZOLEDRONIC ACID , zoledronic acid 4 mg/100 mL injection, 100 mL bag (<i>DBL Zoledronic Acid</i>)

Alteration – Restriction Level

		<i>From</i>	<i>To</i>
11548T	DEFERASIROX , deferasirox 90 mg tablet, 30 (<i>Jadenu</i>)	authority-required	streamlined
11510T	DEFERASIROX , deferasirox 180 mg tablet, 30 (<i>Jadenu</i>)	authority-required	streamlined
11547R	DEFERASIROX , deferasirox 360 mg tablet, 30 (<i>Jadenu</i>)	authority-required	streamlined
9638G	DEFERIPRONE , deferiprone 100 mg/mL oral liquid, 250 mL (<i>Ferriprox</i>)	authority-required	streamlined
6416Q	DEFERIPRONE , deferiprone 500 mg tablet, 100 (<i>Ferriprox</i>)	authority-required	streamlined
6249X	DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL) , doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial (<i>Caelyx, Liposomal Doxorubicin SUN</i>)	authority-required	streamlined
9619G	IBANDRONATE , ibandronate 6 mg/6 mL injection, 6 mL vial (<i>Bondronat</i>)	authority-required	streamlined

6210W	INTERFERON ALFA-2A , interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe (<i>Roferon-A</i>)	authority-required	streamlined
6213B	INTERFERON ALFA-2A , interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe (<i>Roferon-A</i>)	authority-required	streamlined
6423C	LANREOTIDE , lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe (<i>Somatuline Autogel</i>)	authority-required	streamlined
6424D	LANREOTIDE , lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe (<i>Somatuline Autogel</i>)	authority-required	streamlined
11527Q	LANREOTIDE , lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe (<i>Somatuline Autogel</i>)	authority-required	streamlined
6425E	LANREOTIDE , lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe (<i>Somatuline Autogel</i>)	authority-required	streamlined
6332G	LANREOTIDE , lanreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack (<i>Somatuline LA</i>)	authority-required	streamlined
11517E	LENOGRASTIM , lenograstim 13.4 million units (105 microgram) injection, 1 vial (<i>Granocyte 13</i>)	authority-required	streamlined
11530W	LENOGRASTIM , lenograstim 33.6 million units (263 microgram) injection, 1 vial (<i>Granocyte 34</i>)	authority-required	streamlined
10931H	LIPEGFILGRASTIM , lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (<i>Lonquex</i>)	authority-required	streamlined
6227R	OCTREOTIDE , octreotide 50 microgram/mL injection, 5 x 1 mL ampoules (<i>Hospira Pty Limited, Octreotide (SUN), Octreotide MaxRx, Sandostatin 0.05</i>)	authority-required	streamlined
6228T	OCTREOTIDE , octreotide 100 microgram/mL injection, 5 x 1 mL ampoules (<i>Hospira Pty Limited, Octreotide (SUN), Octreotide MaxRx, Sandostatin 0.1</i>)	authority-required	streamlined
6229W	OCTREOTIDE , octreotide 500 microgram/mL injection, 5 x 1 mL ampoules (<i>Hospira Pty Limited, Octreotide (SUN), Octreotide MaxRx, Sandostatin 0.5</i>)	authority-required	streamlined
10566D	OCTREOTIDE , octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)	authority-required	streamlined
10549F	OCTREOTIDE , octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)	authority-required	streamlined
10558Q	OCTREOTIDE , octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)	authority-required	streamlined
6286W	PAMIDRONATE DISODIUM , pamidronate disodium 15 mg/5 mL injection, 5 mL vial (<i>Pamisol</i>)	authority-required	streamlined
6287X	PAMIDRONATE DISODIUM , pamidronate disodium 30 mg/10 mL injection, 10 mL vial (<i>Pamisol</i>)	authority-required	streamlined
6288Y	PAMIDRONATE DISODIUM , pamidronate disodium 60 mg/10 mL injection, 10 mL vial (<i>Pamisol</i>)	authority-required	streamlined
6289B	PAMIDRONATE DISODIUM , pamidronate disodium 90 mg/10 mL injection, 10 mL vial (<i>Pamisol</i>)	authority-required	streamlined
6363X	PEGFILGRASTIM , pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (<i>Neulasta, Ristempa, Tezmota</i>)	authority-required	streamlined
10084R	PLERIXAFOR , plerixafor 24 mg/1.2 mL injection, 1.2 mL vial (<i>Mozobil</i>)	authority-required	streamlined
6469L	THALIDOMIDE , thalidomide 50 mg capsule, 28 (<i>Thalomid</i>)	authority-required	streamlined
9684Q	THALIDOMIDE , thalidomide 100 mg capsule, 28 (<i>Thalomid</i>)	authority-required	streamlined
6280M	VALACICLOVIR , valaciclovir 500 mg tablet, 100 (<i>APO-Valaciclovir, Valaciclovir APOTEX, Valaciclovir RBX, Valtrex</i>)	authority-required	streamlined
9675F	VALGANCICLOVIR , valganciclovir 50 mg/mL powder for oral liquid, 100 mL (<i>Valcyte</i>)	authority-required	streamlined
6357N	VALGANCICLOVIR , valganciclovir 450 mg tablet, 60 (<i>Valcyte, Valganciclovir AN, Valganciclovir Juno, Valganciclovir Mylan, Valganciclovir Sandoz</i>)	authority-required	streamlined
11405G	ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 5 x 5 mL vials (<i>Claris Lifesciences Zoledronic Acid</i>)	authority-required	streamlined

6371H	ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 5 mL vial (<i>APO-Zoledronic Acid, DBL Zoledronic Acid, DEZTRON, Zometa</i>)	authority-required	streamlined
10542W	ZOLEDRONIC ACID , zoledronic acid 4 mg/100 mL injection, 100 mL bag (<i>DBL Zoledronic Acid</i>)	authority-required	streamlined

Advance Notices

1 October 2019

Deletion – Brand

9681M	<i>Prograf XL, LL</i> – TACROLIMUS , tacrolimus 500 microgram modified release capsule, 30
9682N	<i>Prograf XL, LL</i> – TACROLIMUS , tacrolimus 1 mg modified release capsule, 60
9683P	<i>Prograf XL, LL</i> – TACROLIMUS , tacrolimus 5 mg modified release capsule, 30
11405G	<i>Claris Lifesciences Zoledronic Acid, DZ</i> – ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 5 x 5 mL vials

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand

9597D	<i>Azacitidine Juno, JO</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
9598E	<i>Azacitidine Juno, JO</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial

Deletions

Deletion – Item

10914K	RIBAVIRIN , ribavirin 200 mg tablet, 28 (<i>Ibavyr</i>)
10929F	RIBAVIRIN , ribavirin 200 mg tablet, 28 (<i>Ibavyr</i>)
10548E	ZOLEDRONIC ACID , zoledronic acid 4 mg/100 mL injection, 100 mL vial (<i>Zoledronic Acid 4 mg/100 mL APOTEX</i>)

Alterations

Alteration – Item Description

From	
5794Y	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe (<i>Mircera</i>)
To	
5794Y	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 0.3 mL syringe (<i>Mircera</i>)
From	
5795B	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe (<i>Mircera</i>)
To	
5795B	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 0.3 mL syringe (<i>Mircera</i>)
From	
5796C	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe (<i>Mircera</i>)
To	
5796C	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 0.3 mL syringe (<i>Mircera</i>)
From	
5797D	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe (<i>Mircera</i>)
To	
5797D	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 0.3 mL syringe (<i>Mircera</i>)
From	
5798E	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe (<i>Mircera</i>)
To	
5798E	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 0.3 mL syringe (<i>Mircera</i>)

<i>From</i> 5799F	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe (<i>Mircera</i>)
<i>To</i> 5799F	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 0.3 mL syringe (<i>Mircera</i>)
<i>From</i> 5800G	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe (<i>Mircera</i>)
<i>To</i> 5800G	METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA , methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 0.6 mL syringe (<i>Mircera</i>)

Alteration – Maximum Quantity

		<i>From</i>	<i>To</i>
11400B	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Renflexis</i>)	4	5
11423F	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Renflexis</i>)	4	5
11449N	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Renflexis</i>)	4	5
11461F	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Renflexis</i>)	4	5
11486M	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Renflexis</i>)	4	5
11514B	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Renflexis</i>)	4	5
11605T	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Renflexis</i>)	4	5

Advance Notices

1 October 2019

Deletion – Brand

9664P	<i>Prograf XL, LL</i> – TACROLIMUS , tacrolimus 500 microgram modified release capsule, 30
9665Q	<i>Prograf XL, LL</i> – TACROLIMUS , tacrolimus 1 mg modified release capsule, 60
9666R	<i>Prograf XL, LL</i> – TACROLIMUS , tacrolimus 5 mg modified release capsule, 30
11388J	<i>Claris Lifesciences Zoledronic Acid, DZ</i> – ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 5 x 5 mL vials

Highly Specialised Drugs Program (Community Access)

Advance Notices

1 January 2020

Deletion – Brand

10357D	<i>Abacavir/Lamivudine 600/300 APOTEX, TX</i> – ABACAVIR + LAMIVUDINE , abacavir 600 mg + lamivudine 300 mg tablet, 30

1 March 2020

Deletion – Brand

10314W	<i>Eviplera, GI</i> – TENOFOVIR + EMTRICITABINE + RILPIVIRINE , tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + rilpivirine 25 mg tablet, 30
10307L	<i>Stribild, GI</i> – TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT , tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30

Botulinum Toxin Program

Additions

Addition – Item

11751L	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)

Growth Hormone Program

Alterations

Alteration – Item Description

<i>From</i> 10891F	SOMATROPIN , somatropin 400 microgram injection, syringe [7] (&) inert substance diluent, syringe [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)

<i>To</i>	
10891F	SOMATROPIN , somatropin 400 microgram injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
<i>From</i>	
10902T	SOMATROPIN , somatropin 400 microgram injection, syringe [7] (&) inert substance diluent, syringe [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
<i>To</i>	
10902T	SOMATROPIN , somatropin 400 microgram injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
<i>From</i>	
10908D	SOMATROPIN , somatropin 400 microgram injection, syringe [7] (&) inert substance diluent, syringe [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
<i>To</i>	
10908D	SOMATROPIN , somatropin 400 microgram injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
Alteration – Restriction	
10891F	SOMATROPIN , somatropin 400 microgram injection, injectionsyringe [7] (&) inert substance diluent, diluentsyringe [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10456H	SOMATROPIN , somatropin 600 microgram injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10479M	SOMATROPIN , somatropin 800 microgram injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10480N	SOMATROPIN , somatropin 1 mg injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10453E	SOMATROPIN , somatropin 1.2 mg injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10488B	SOMATROPIN , somatropin 1.4 mg injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10454F	SOMATROPIN , somatropin 1.6 mg injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10500P	SOMATROPIN , somatropin 1.8 mg injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10428W	SOMATROPIN , somatropin 2 mg injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10452D	SOMATROPIN , somatropin 4 mg injection [1 vial] (&) inert substance diluent [1 vial], 1 pack (<i>Zomacton</i>)
10440L	SOMATROPIN , somatropin 10 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack (<i>Zomacton</i>)
10482Q	SOMATROPIN , somatropin 6 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack (<i>Humatrope</i>)
10487Y	SOMATROPIN , somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack (<i>Humatrope</i>)
10476J	SOMATROPIN , somatropin 24 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack (<i>Humatrope</i>)
10443P	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 (<i>Genotropin GoQuick</i>)
11493X	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 (<i>Genotropin GoQuick</i>)
10431B	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 (<i>Genotropin GoQuick</i>)
11495B	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 (<i>Genotropin GoQuick</i>)
10427T	SOMATROPIN , somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (<i>Scitropin A</i>)
10432C	SOMATROPIN , somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
10469B	SOMATROPIN , somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)
10507B	SOMATROPIN , somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (<i>Omnitrope Surepal 5</i>)
10462P	SOMATROPIN , somatropin 6 mg/1.03 mL injection, 1.03 mL cartridge (<i>Saizen</i>)

10439K	SOMATROPIN , somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)
10441M	SOMATROPIN , somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge (<i>SciTropin A</i>)
10451C	SOMATROPIN , somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
10478L	SOMATROPIN , somatropin 10 mg/2 mL injection, 2 mL cartridge (<i>NutropinAq</i>)
10506Y	SOMATROPIN , somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge (<i>Omnitrope Surepal 10</i>)
11650E	SOMATROPIN , somatropin 10 mg/2 mL injection, 2 mL cartridge (<i>NutropinAq</i>)
10483R	SOMATROPIN , somatropin 12 mg/1.5 mL injection, 1.5 mL cartridge (<i>Saizen</i>)
10449Y	SOMATROPIN , somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
10468Y	SOMATROPIN , somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)
10490D	SOMATROPIN , somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge (<i>Omnitrope Surepal 15</i>)
10497L	SOMATROPIN , somatropin 20 mg/2.5 mL injection, 2.5 mL cartridge (<i>Saizen</i>)

Advance Notices

1 October 2019

Deletion – Brand

10440L	<i>Zomacton, FP</i> – SOMATROPIN , somatropin 10 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack
10455G	<i>Zomacton, FP</i> – SOMATROPIN , somatropin 10 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack
6310D	<i>Zomacton, FP</i> – SOMATROPIN , somatropin 10 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

Opiate Dependence Treatment Program

Additions

Addition – Item

11759X	BUPRENORPHINE , buprenorphine 8 mg/0.16 mL modified release injection, 0.16 mL syringe (<i>Buvidal Weekly</i>)
11774Q	BUPRENORPHINE , buprenorphine 16 mg/0.32 mL modified release injection, 0.32 mL syringe (<i>Buvidal Weekly</i>)
11773P	BUPRENORPHINE , buprenorphine 24 mg/0.48 mL modified release injection, 0.48 mL syringe (<i>Buvidal Weekly</i>)
11766G	BUPRENORPHINE , buprenorphine 32 mg/0.64 mL modified release injection, 0.64 mL syringe (<i>Buvidal Weekly</i>)
11754P	BUPRENORPHINE , buprenorphine 64 mg/0.18 mL modified release injection, 0.18 mL syringe (<i>Buvidal Monthly</i>)
11767H	BUPRENORPHINE , buprenorphine 96 mg/0.27 mL modified release injection, 0.27 mL syringe (<i>Buvidal Monthly</i>)
11768J	BUPRENORPHINE , buprenorphine 128 mg/0.36 mL modified release injection, 0.36 mL syringe (<i>Buvidal Monthly</i>)

Repatriation Pharmaceutical Benefits

Deletions

Deletion – Item

2273P	ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE , alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack (<i>Fosamax Plus D-Cal</i>)

Alterations

Alteration – Item Description

<i>From</i>	
4010C	AMOROLFINE , amorolfine 5% application, 5 mL (<i>Aporyl, Loceryl, Myconail, Pharmacy Action Anti-Fungal Nail Treatment</i>)
<i>To</i>	
4010C	AMOROLFINE , amorolfine 5% solution, 5 mL (<i>Aporyl, Loceryl, Myconail, Pharmacy Action Anti-Fungal Nail Treatment</i>)
<i>From</i>	
4306P	LUBRICATING AGENT , lubricating agent jelly, 100 g (<i>Lubri-Gel</i>)
<i>To</i>	
4306P	LUBRICATING AGENT , lubricating agent gel, 100 g (<i>Lubri-Gel</i>)
<i>From</i>	
4386W	SALICYLIC ACID + LACTIC ACID , salicylic acid 16.7% + lactic acid 16.7% application, 15 mL (<i>Duofilm Solution</i>)

To
4386W **SALICYLIC ACID + LACTIC ACID**, salicylic acid 16.7% + lactic acid 16.7% solution, 15 mL (*Duofilm Solution*)

Advance Notices

1 October 2019

Deletion – Brand

4042R *Calmurid, OL* – **UREA**, urea 10% cream, 100 g

About the Schedule

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

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

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

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

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

Symbols and Abbreviations Used in the Schedule

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

Restricted Benefits

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

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

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

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

Guidelines and General Statements

General Statement for Drugs for the Treatment of Hepatitis C

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

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a medical practitioner or an authorised nurse practitioner¹ experienced in the treatment of chronic hepatitis C infection; or in consultation with a gastroenterologist, hepatologist or infectious diseases physician experienced in the treatment of chronic hepatitis C infection.

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

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

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

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

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

HEPATITIS C - NON-CIRRHOTIC PATIENTS

	TREATMENT NAÏVE	TREATMENT EXPERIENCED
Genotype 1	LEDIPASVIR + SOFOSBUVIR [8 or 12 weeks] ² OR DACLATASVIR and SOFOSBUVIR [12 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR GRAZOPREVR + ELBASVIR [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] OR GLECAPREVR with PIBRENTASVIR [8 weeks]	LEDIPASVIR + SOFOSBUVIR [12 weeks] OR DACLATASVIR and SOFOSBUVIR [12 or 24 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR GRAZOPREVR + ELBASVIR [12 weeks] OR GRAZOPREVR + ELBASVIR and RBV [16 weeks] ³ OR SOFOSBUVIR + VELPATASVIR [12 weeks] OR GLECAPREVR + PIBRENTASVIR [8, 12 and 16 weeks] ⁴ OR SOFOSBUVIR + VELPATASVIR + VOXILAPREVR [12 weeks] ⁵

Genotype 2	SOFOSBUVIR and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] OR GLECAPREVIR + PIBRENTASVIR [8 weeks]	SOFOSBUVIR and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] OR GLECAPREVIR + PIBRENTASVIR [8 weeks] OR SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] ⁵
Genotype 3	DACLATASVIR and SOFOSBUVIR [12 weeks] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] OR GLECAPREVIR + PIBRENTASVIR [8 weeks]	DACLATASVIR and SOFOSBUVIR [12 weeks] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] OR GLECAPREVIR + PIBRENTASVIR [16 weeks] OR SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] ⁵
Genotype 4	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR GRAZOPREVIR + ELBASVIR [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] OR GLECAPREVIR + PIBRENTASVIR [8 weeks]	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR GRAZOPREVIR + ELBASVIR [12 weeks] OR GRAZOPREVIR + ELBASVIR and RBV [16 weeks] ³ OR SOFOSBUVIR + VELPATASVIR [12 weeks] OR GLECAPREVIR with PIBRENTASVIR [8 weeks] OR SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] ⁵
Genotype 5 & 6	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] OR GLECAPREVIR + PIBRENTASVIR [8 weeks]	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] OR GLECAPREVIR + PIBRENTASVIR [8 weeks] SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] ⁵

KEY

PEG-IFN - peginterferon alfa-2a

RBV - ribavirin

HEPATITIS C – CIRRHOTIC PATIENTS

	TREATMENT NAÏVE	TREATMENT EXPERIENCED
Genotype 1	LEDIPASVIR + SOFOSBUVIR [12 weeks] OR DACLATASVIR and SOFOSBUVIR and RBV [12 weeks] OR DACLATASVIR and SOFOSBUVIR [24 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR GRAZOPREVIR + ELBASVIR [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks] ⁶ OR GLECAPREVIR + PIBRENTASVIR [12 weeks]	LEDIPASVIR + SOFOSBUVIR [24 weeks] OR DACLATASVIR and SOFOSBUVIR [24 weeks] OR DACLATASVIR and SOFOSBUVIR and RBV [12 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR GRAZOPREVIR + ELBASVIR [12 weeks] OR GRAZOPREVIR + ELBASVIR and RBV [16 weeks] ³ OR SOFOSBUVIR + VELPATASVIR [12 weeks] ⁶ OR GLECAPREVIR + PIBRENTASVIR [12 and 16 weeks] ⁷ OR SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] ⁵

Genotype 2	SOFOSBUVIR and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]⁶ OR GLECAPREVIR with PIBRENTASVIR [12 weeks]	SOFOSBUVIR and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]⁶ OR GLECAPREVIR + PIBRENTASVIR [12 weeks] OR SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks]⁵
Genotype 3	SOFOSBUVIR and RBV [24 weeks] OR DACLATASVIR and SOFOSBUVIR [24 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR DACLATASVIR and SOFOSBUVIR and RBV [12 or 24 weeks]⁸ OR SOFOSBUVIR + VELPATASVIR [12 weeks]^{6, 9} OR GLECAPREVIR + PIBRENTASVIR [12 weeks]	DACLATASVIR and SOFOSBUVIR [24 weeks] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR DACLATASVIR and SOFOSBUVIR and RBV [12 or 24 weeks]⁸ OR SOFOSBUVIR + VELPATASVIR [12 weeks]^{6, 9} OR GLECAPREVIR + PIBRENTASVIR [16 weeks] OR SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks]⁵
Genotype 4	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR GRAZOPREVIR + ELBASVIR [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]⁶ OR GLECAPREVIR + PIBRENTASVIR [12 weeks]	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR GRAZOPREVIR + ELBASVIR [12 weeks] OR GRAZOPREVIR + ELBASVIR and RBV [16 weeks]³ OR SOFOSBUVIR + VELPATASVIR [12 weeks]⁶ OR GLECAPREVIR with PIBRENTASVIR [12 weeks] OR SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks]⁵
Genotype 5 & 6	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]⁶ OR GLECAPREVIR + PIBRENTASVIR [12 weeks]	SOFOSBUVIR and PEG-IFN and RBV [12 weeks] OR SOFOSBUVIR + VELPATASVIR [12 weeks]⁶ OR GLECAPREVIR with PIBRENTASVIR [12 weeks] OR SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks]⁵

KEY

PEG-IFN - peginterferon alfa-2a

RBV – ribavirin

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

² LEDIPASVIR + SOFOSBUVIR [8 or 12 weeks] for treatment-naïve, non-cirrhotic patients:

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

³ GRAZOPREVIR + ELBASVIR and RBV [16 weeks] for treatment-experienced, non-cirrhotic and cirrhotic patients, treatment for 16 weeks in patients with genotype 1a or 4 HCV who have experienced on-treatment virologic failure to prior treatment.

⁴ GLECAPREVIR + PIBRENTASVIR [8 or 12 or 16 weeks]:

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

⁵ SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] only for patients who have failed an NS5A inhibitor.

⁶ SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with decompensated cirrhosis. Use in combination with ribavirin.

⁷ GLECAPREVIR + PIBRENTASVIR [12 or 16 weeks]:

- treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
- treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.

-
- ⁸. DACLATASVIR and SOFOSBUVIR and RBV [12 or 24 weeks] for cirrhotic patients. Consider a 24 week regimen of where clinically appropriate.
- ⁹. SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with genotype 3 infection with compensated cirrhosis. Consider addition of ribavirin.

Pharmaceutical Benefits Schedules

Prescriber Bag

▪ ADRENALINE (EPINEPHRINE)

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

3451P	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	21.14	Link Medical Products Pty Ltd [LM]

▪ ATROPINE SULFATE

atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules

3453R	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	23.15	Pfizer Australia Pty Ltd [PF]

▪ BENZATHINE BENZYL PENICILLIN

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

11755Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	298.66	Bicillin L-A [PF]

▪ BENZATROPINE

benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials

11265X	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	116.38	Benzatropine Injection [FF]

▪ BENZYL PENICILLIN

benzylpenicillin 600 mg injection, 1 vial

3486L	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	5	*41.19	BenPen [CS]

OR

▪ PROCAINE BENZYL PENICILLIN (PROCAINE PENICILLIN)

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

3485K	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	74.83	Cilicaine [QA]

▪ BENZYL PENICILLIN

benzylpenicillin 3 g injection, 1 vial

3487M	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	21.06	BenPen [CS]

▪ CHLORPROMAZINE

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

3455W	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	21.40	Largactil [SW]

OR

▪ HALOPERIDOL

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

3456X	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	22.68	Serenace [QA]

▪ CLONAZEPAM

clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL

3478C	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	‡1	15.23	Rivotril [RO]

■ DEXAMETHASONE PHOSPHATE

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

3472R	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	17.60	^a Dexamethasone Mylan [AF]	^a Hospira Pty Limited [PF]

OR

■ HYDROCORTISONE SODIUM SUCCINATE

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

3470P	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	2	*21.29	Solu-Cortef [PF]

OR

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

3471Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	20.24	Solu-Cortef [PF]

■ DIAZEPAM

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

3458B	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	17.50	Hospira Pty Limited [PF]

■ DIPHTHERIA + TETANUS VACCINE

diphtheria 2 units + tetanus 20 units vaccine injection, 5 x 0.5 mL syringes

3463G	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	2	*128.37	ADT Booster [CS]

■ FUROSEMIDE (FRUSEMIDE)

furosemide (frusemide) 20 mg/2 mL injection, 5 x 2 mL ampoules

3466K	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	12.80	^a Frusemide-Clarix [BX] ^a Lasix [SW]	^a Frusemide Sandoz [SZ]

■ GLUCAGON HYDROCHLORIDE

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

3467L	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	49.12	Glucagen Hypokit [NO]

■ GLYCERYL TRINITRATE

glyceryl trinitrate 400 microgram/actuation spray, 200 actuations

3475X	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	‡1	23.40	Nitrolingual Pumpspray [SW]

■ HYOSCINE BUTYLBROMIDE

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

3473T	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	23.82	^a Buscopan [VZ]	^a HYOSCINE BUTYLBROMIDE SXP [XC]

■ LIDOCAINE (LIGNOCAINE)

lidocaine (lignocaine) hydrochloride monohydrate 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules

10209H	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	39.01	Pfizer Australia Pty Ltd [PF]

■ METHOXYFLURANE

methoxyflurane 99.9% (999 mg/g) inhalation solution, 3 mL bottle

3489P	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	43.65	Penthrox [DV]

▪ METOCLOPRAMIDE

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

3476Y	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	17.19	Maxolon [IL]

OR

▪ PROCHLORPERAZINE

prochlorperazine mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules

3477B	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	21.16	Stemetil [SW]

▪ MIDAZOLAM

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

10178Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	40.71	Pfizer Australia Pty Ltd [PF]

▪ MORPHINE

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

3479D	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	22.31	^a Hospira Pty Limited [PF]	^a MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]

OR

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

10868B	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	24.27	Morphine Juno [JU]

OR

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

3480E	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	24.41	^a Hospira Pty Limited [PF]	^a MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]

OR

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

10862Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	20.91	Morphine Juno [JU]

▪ NALOXONE

naloxone hydrochloride 400 microgram/mL injection, 10 x 1 mL ampoules

11233F	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	1	95.26	^a NARCAN [FF]

OR

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

10786Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	*95.27	^a Naloxone Hydrochloride (DBL) [PF]	^a Naloxone Juno [JU]

▪ OXYTOCIN

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

10251M	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	61.48	Oxytocin Sandoz [SZ]

▪ PHYTOMENADIONE

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

10213M	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	24.97	Konaktion MM [PB]

PROMETHAZINE

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

	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
3488N	2	*35.07	Hospira Pty Limited [PF]

NP

SALBUTAMOL

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

	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3496B	‡1	15.48	^a APO-Salbutamol [TX]	^a Salbutamol Actavis [EA]
			^a Salbutamol AN [ED]	^a Salbutamol Cipla [LR]
		15.73	^a Asmol 2.5 uni-dose [AF]	

OR

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

	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
11125M	‡1	15.82	Ventolin Nebules [GK]

NP

OR

salbutamol 100 microgram/actuation inhalation, 200 actuations

	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
3495Y	‡1	15.67	^a Asmol CFC-free [AL]
		17.50	^a Ventolin CFC-free [GK]

NP

SALBUTAMOL

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

	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3497C	‡1	15.69	^a APO-Salbutamol [TX]	^a Salbutamol Actavis [EA]
			^a Salbutamol AN [ED]	^a Salbutamol Cipla [LR]
		15.94	^a Asmol 5 uni-dose [AF]	

OR

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

	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
11088N	‡1	15.95	Ventolin Nebules [GK]

NP

TRAMADOL

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

	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3484J	1	14.33	^a Tramadol ACT [JO]	^a Tramadol AN [JU]
			^a Tramadol Sandoz [SZ]	^a Tramal 100 [CS]

NP

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ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

STOMATOLOGICAL PREPARATIONS

Antifungives and antiseptics for local oral treatment

AMPHOTERICIN B

amphotericin B 10 mg lozenge, 20

2931G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	15.74	16.99	Fungilin [QA]

amphotericin B 10 mg lozenge, 20

3306B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	15.74	16.99	Fungilin [QA]

Other agents for local oral treatment

BENZYLAMINE

Restricted benefit

Mucositis

Clinical criteria:

- The condition must be radiation induced.

benzylamine hydrochloride 0.15% mouthwash, 500 mL

1121B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	22.67	23.92	Diffiam [IL]

BENZYLAMINE

Restricted benefit

Mucositis

Clinical criteria:

- The condition must be radiation induced.

benzylamine hydrochloride 0.15% mouthwash, 500 mL

5032W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	±1	..	..	22.67	23.92	Diffiam [IL]

DRUGS FOR ACID RELATED DISORDERS

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

H2-receptor antagonists

CIMETIDINE

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

cimetidine 400 mg tablet, 60

1158Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	20.48	21.73	Magicul 400 [AF]

FAMOTIDINE

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

famotidine 20 mg tablet, 60

2487X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.33	16.58	^a Ausfam 20 [RW] ^a Famotidine Sandoz [SZ]	^a Famotidine AN [EA] ^a GenRx Famotidine [GX]

famotidine 40 mg tablet, 30

2488Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.33	16.58	^a Ausfam 40 [RW] ^a Famotidine Sandoz [SZ]	^a Famotidine AN [EA] ^a GenRx Famotidine [GX]

NIZATIDINE

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

nizatidine 300 mg capsule, 30

1504E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.92	23.17	^a Nizac [RF]	^a Tacidine [AF]
			^B 6.61	28.53	23.17	^a Tazac [RW]	

nizatidine 150 mg capsule, 60

1505F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.92	23.17	^a Nizac [RF]	^a Tacidine [AF]
			^B 6.61	28.53	23.17	^a Tazac [RW]	

■ RANITIDINE

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

ranitidine 300 mg tablet, 30

1977C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.94	16.19	^a APO-Ranitidine [TX]	^a Ausran [RW]
						^a Chem mart Ranitidine [CH]	^a Rani 2 [AF]
						^a Ranitidine GH [GQ]	^a Ranitidine Sandoz [SZ]
						^a Terry White Chemists Ranitidine [TW]	
			^B 1.68	16.62	16.19	^a Zantac [AS]	

ranitidine 150 mg/10 mL oral liquid, 300 mL

8162N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*28.73	29.98	Zantac Syrup [AS]

■ RANITIDINE

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

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

ranitidine 150 mg effervescent tablet, 30

1937Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	^B 1.16	*16.55	16.64	^a Zantac [AS]

ranitidine 150 mg tablet, 60

1978D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	5	..	14.94	16.19	^a APO-Ranitidine [TX]	^a Ausran [RW]
						^a Chem mart Ranitidine [CH]	^a Rani 2 [AF]
						^a Ranitidine AN [EA]	^a Ranitidine GH [GQ]
						^a Ranitidine Sandoz [SZ]	^a Terry White Chemists Ranitidine [TW]
			^B 1.68	16.62	16.19	^a Zantac [AS]	

Proton pump inhibitors**■ ESOMEPRAZOLE**

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

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Standard dose proton pump inhibitors are appropriate step-down therapy from high dose proton pump inhibitors.

Note No 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

Gastro-oesophageal reflux disease

Clinical criteria:

- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

esomeprazole 40 mg enteric capsule, 30

10330Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	22.20	23.45	^a Esomeprazole ACTAVIS [EA]	^a Noxicid Caps [AL]

esomeprazole 40 mg enteric tablet, 30

8601Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	22.20	23.45	^a Esomeprazole Apotex [TX]	^a Esomeprazole GH [GQ]
						^a Esomeprazole GxP [AF]	^a Esomeprazole RBX [RA]
						^a Esomeprazole Sandoz [SZ]	^a Esomeprazole SZ [HX]
						^a Nexazole [RW]	^a Nexole [RF]

^a Pharmacor Esomeprazole [CR]

^b3.58 25.78 23.45 ^a Nexium [AP]

■ ESOMEPRAZOLE

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

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Standard dose proton pump inhibitors are appropriate step-down therapy from high dose proton pump inhibitors.

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.

Authority required

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

Clinical criteria:

- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

Authority required

Scleroderma oesophagus

Clinical criteria:

- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

esomeprazole 40 mg enteric capsule, 30

10331R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.20	23.45	^a Esomeprazole ACTAVIS [EA]	^a Noxicid Caps [AL]

esomeprazole 40 mg enteric tablet, 30

3401B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.20	23.45	^a Esomeprazole Apotex [TX] ^a Esomeprazole GxP [AF] ^a Esomeprazole Sandoz [SZ] ^a Nexazole [RW] ^a Pharmacor Esomeprazole [CR]	^a Esomeprazole GH [GQ] ^a Esomeprazole RBX [RA] ^a Esomeprazole SZ [HX] ^a Nexole [RF]
			^b 3.58	25.78	23.45	^a Nexium [AP]	

■ ESOMEPRAZOLE

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

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

Authority required (STREAMLINED)

8780

Scleroderma oesophagus

Authority required (STREAMLINED)

8827

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

esomeprazole 20 mg enteric tablet, 30

8600P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.79	19.04	^a Esomeprazole Apotex [TX] ^a Esomeprazole GxP [AF] ^a Esomeprazole Sandoz [SZ] ^a Nexazole [RW] ^a Pharmacor Esomeprazole [CR]	^a Esomeprazole GH [GQ] ^a Esomeprazole RBX [RA] ^a Esomeprazole SZ [HX] ^a Nexole [RF]
			^b 3.58	21.37	19.04	^a Nexium [AP]	

esomeprazole 20 mg enteric capsule, 30

10343J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.79	19.04	^a Esomeprazole ACTAVIS [EA]	^a Noxicid Caps [AL]

■ ESOMEPRAZOLE

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

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

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

Authority required (STREAMLINED)

8776

Gastro-oesophageal reflux disease

Clinical criteria:

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

esomeprazole 20 mg enteric tablet, 30

11692J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.79	19.04	^a Esomeprazole Apotex [TX] ^a Esomeprazole GxP [AF] ^a Esomeprazole Sandoz [SZ] ^a Nexazole [RW] ^a Pharmacor Esomeprazole [CR]	^a Esomeprazole GH [GQ] ^a Esomeprazole RBX [RA] ^a Esomeprazole SZ [HX] ^a Nexole [RF]
			^B 3.58	21.37	19.04	^a Nexium [AP]	

esomeprazole 20 mg enteric capsule, 30

11687D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.79	19.04	^a Esomeprazole ACTAVIS [EA]	^a Noxicid Caps [AL]

■ **ESOMEPRAZOLE**

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

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

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

Authority required (STREAMLINED)

8775

Peptic ulcer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

Authority required (STREAMLINED)

8774

Gastro-oesophageal reflux disease

Clinical criteria:

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

esomeprazole 20 mg enteric tablet, 30

8886Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.79	19.04	^a Esomeprazole Apotex [TX] ^a Esomeprazole GxP [AF] ^a Esomeprazole Sandoz [SZ] ^a Nexazole [RW] ^a Pharmacor Esomeprazole [CR]	^a Esomeprazole GH [GQ] ^a Esomeprazole RBX [RA] ^a Esomeprazole SZ [HX] ^a Nexole [RF]
			^B 3.58	21.37	19.04	^a Nexium [AP]	

esomeprazole 20 mg enteric capsule, 30

10295W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.79	19.04	^a Esomeprazole ACTAVIS [EA]	^a Noxicid Caps [AL]

■ **LANSOPRAZOLE**

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

lansoprazole 15 mg enteric capsule, 30

8198L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.85	16.10	Zopral [AF]

lansoprazole 15 mg orally disintegrating tablet, 28

9331D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.62	15.87	^a APO-Lansoprazole ODT [TX] ^a Zopral ODT [AF]	^a Lansoprazole ODT GH [GQ]
			^B 4.81	19.43	15.87	^a Zoton FasTabs [PF]	

■ LANSOPRAZOLE

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

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

Authority required (STREAMLINED)**8780**

Scleroderma oesophagus

lansoprazole 30 mg enteric capsule, 28

2241Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.11	18.36	^a APO-Lansoprazole [TX] ^a Zopral [AF]	^a Lanzopran [RA]

lansoprazole 30 mg orally disintegrating tablet, 28

9478W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.11	18.36	^a APO-Lansoprazole ODT [TX] ^a Zopral ODT [AF]	^a Lansoprazole ODT GH [GQ]
			^B 4.81	21.92	18.36	^a Zoton FasTabs [PF]	

■ LANSOPRAZOLE

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

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

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

Authority required (STREAMLINED)**8776**

Gastro-oesophageal reflux disease

Clinical criteria:

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

lansoprazole 30 mg enteric capsule, 28

11669E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.11	18.36	^a APO-Lansoprazole [TX] ^a Zopral [AF]	^a Lanzopran [RA]

lansoprazole 30 mg orally disintegrating tablet, 28

11697P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.11	18.36	^a APO-Lansoprazole ODT [TX] ^a Zopral ODT [AF]	^a Lansoprazole ODT GH [GQ]
			^B 4.81	21.92	18.36	^a Zoton FasTabs [PF]	

■ LANSOPRAZOLE

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

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

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

Authority required (STREAMLINED)**8775**

Peptic ulcer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

Authority required (STREAMLINED)**8774**

Gastro-oesophageal reflux disease

Clinical criteria:

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

lansoprazole 30 mg enteric capsule, 28

2240X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.11	18.36	^a APO-Lansoprazole [TX] ^a Zopral [AF]	^a Lanzopran [RA]

lansoprazole 30 mg orally disintegrating tablet, 28

9477T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.11	18.36	^a APO-Lansoprazole ODT [TX] ^a Zopral ODT [AF]	^a Lansoprazole ODT GH [GQ]
			^b 4.81	21.92	18.36	^a Zoton FasTabs [PF]	

■ OMEPRAZOLE**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.**Restricted benefit**

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

Restricted benefit

Zollinger-Ellison syndrome

omeprazole 10 mg enteric tablet, 30

8332M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.10	16.35	Losec Tablets [AP]

■ OMEPRAZOLE**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.**Authority required (STREAMLINED)****8780**

Scleroderma oesophagus

Authority required (STREAMLINED)**8866**

Zollinger-Ellison syndrome

omeprazole 20 mg enteric capsule, 30

1327W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.91	17.16	^a APO-Omeprazole [TX] ^a Omeprazole Sandoz [HX] ^a Pharmacor Omeprazole 20 [CR]	^a Maxor [AF] ^a Pemzo [RW] ^a Probitor [SZ]

omeprazole 20 mg enteric tablet, 30

8333N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.91	17.16	^a APO-Omeprazole [TX] ^a Omeprazole AN [EA] ^a Ozmepr [ZP]	^a Meprazol [SZ] ^a Omeprazole generichealth [GQ] ^a Pharmacor Omeprazole [CR]

omeprazole 20 mg enteric tablet, 30

9110L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.91	17.16	^a Acimax Tablets [AL] ^a Omeprazole Sandoz [SZ] ^b 7.36	^a Omepral [ZA]
				23.27	17.16	^a Losec Tablets [AP]	

■ OMEPRAZOLE

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

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

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

Authority required (STREAMLINED)

8776

Gastro-oesophageal reflux disease

Clinical criteria:

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

omeprazole 20 mg enteric capsule, 30

11682W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.91	17.16	^a APO-Omeprazole [TX] ^a Omeprazole Sandoz [HX] ^a Pharmacor Omeprazole 20 [CR]	^a Maxor [AF] ^a Pemzo [RW] ^a Probitor [SZ]

omeprazole 20 mg enteric tablet, 30

11677N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.91	17.16	^a Acimax Tablets [AL] ^a Omeprazole Sandoz [SZ]	^a Omepral [ZA]
			^B 7.36	23.27	17.16	^a Losec Tablets [AP]	

omeprazole 20 mg enteric tablet, 30

11683X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.91	17.16	^a APO-Omeprazole [TX] ^a Omeprazole AN [EA] ^a Ozmepr [ZP]	^a Meprazol [SZ] ^a Omeprazole generichealth [GQ] ^a Pharmacor Omeprazole [CR]

■ OMEPRAZOLE

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

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

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

Authority required (STREAMLINED)

8775

Peptic ulcer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

Authority required (STREAMLINED)

8774

Gastro-oesophageal reflux disease

Clinical criteria:

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

omeprazole 20 mg enteric capsule, 30

1326T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	15.91	17.16	^a APO-Omeprazole [TX] ^a Omeprazole Sandoz [HX] ^a Pharmacor Omeprazole 20 [CR]	^a Maxor [AF] ^a Pemzo [RW] ^a Probitor [SZ]

omeprazole 20 mg enteric tablet, 30

8331L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	15.91	17.16	^a APO-Omeprazole [TX]	^a Meprazol [SZ]

NP						^a Omeprazole AN [EA]	^a Omeprazole generichealth [GQ]
						^a Ozmep [ZP]	^a Pharmacor Omeprazole [CR]
omeprazole 20 mg enteric tablet, 30							
9109K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	15.91	17.16	^a Acimax Tablets [AL]	^a Omepral [ZA]
						^a Omeprazole Sandoz [SZ]	
			^B 7.36	23.27	17.16	^a Losec Tablets [AP]	

■ PANTOPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

Restricted benefit

Zollinger-Ellison syndrome

pantoprazole 20 mg enteric tablet, 30

8399C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		Brand Name and Manufacturer
NP	1	5	..	12.73	13.98	^a APO-Pantoprazole [TX]		^a APOTEX-Pantoprazole [GX]
						^a Ozpan [RA]		^a Panthron [ER]
						^a Panto [TK]		^a Pantofast 20 [RZ]
						^a Pantoprazole AN [EA]		^a Pantoprazole APOTEX [TY]
						^a Pantoprazole generichealth [HQ]		^a Pantoprazole Sandoz [SZ]
						^a Salpraz [AF]		^a Somac [NQ]
						^a Sozol [RW]		

■ PANTOPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

Authority required (STREAMLINED)

8780

Scleroderma oesophagus

Authority required (STREAMLINED)

8866

Zollinger-Ellison syndrome

pantoprazole 40 mg enteric coated granules, 30 sachets

9424B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		
NP	1	5	..	32.60	33.85	Somac [NQ]		

pantoprazole 40 mg enteric tablet, 30

8008L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		Brand Name and Manufacturer
NP	1	5	..	14.03	15.28	^a APO-Pantoprazole [TX]		^a APOTEX-Pantoprazole [GX]
						^a I-Pantoprazole [CR]		^a Ozpan [RA]
						^a Panthron [ER]		^a Panto [TK]
						^a Pantoprazole Actavis [ED]		^a Pantoprazole AN [EA]
						^a Pantoprazole APOTEX [TY]		^a Pantoprazole generichealth [HQ]
						^a Pantoprazole GH [GQ]		^a Pantoprazole Sandoz [SZ]
						^a Salpraz [AF]		^a Somac [NQ]
						^a Sozol [RW]		

■ PANTOPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

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

Authority required (STREAMLINED)

8776

Gastro-oesophageal reflux disease

Clinical criteria:

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

pantoprazole 40 mg enteric coated granules, 30 sachets

11678P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	32.60	33.85	Somac [NQ]

pantoprazole 40 mg enteric tablet, 30

11681T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.03	15.28	^a APO-Pantoprazole [TX] ^a I-Pantoprazole [CR] ^a Panthron [ER] ^a Pantoprazole Actavis [ED] ^a Pantoprazole APOTEX [TY] ^a Pantoprazole GH [GQ] ^a Salpraz [AF] ^a Sozol [RW]	^a APOTEX-Pantoprazole [GX] ^a Ozpan [RA] ^a Panto [TK] ^a Pantoprazole AN [EA] ^a Pantoprazole generichealth [HQ] ^a Pantoprazole Sandoz [SZ] ^a Somac [NQ]

■ PANTOPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

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

Authority required (STREAMLINED)**8775**

Peptic ulcer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

Authority required (STREAMLINED)**8774**

Gastro-oesophageal reflux disease

Clinical criteria:

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

pantoprazole 40 mg enteric coated granules, 30 sachets

9423Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	32.60	33.85	Somac [NQ]

pantoprazole 40 mg enteric tablet, 30

8007K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	14.03	15.28	^a APO-Pantoprazole [TX] ^a I-Pantoprazole [CR] ^a Panthron [ER] ^a Pantoprazole Actavis [ED] ^a Pantoprazole APOTEX [TY] ^a Pantoprazole GH [GQ] ^a Salpraz [AF] ^a Sozol [RW]	^a APOTEX-Pantoprazole [GX] ^a Ozpan [RA] ^a Panto [TK] ^a Pantoprazole AN [EA] ^a Pantoprazole generichealth [HQ] ^a Pantoprazole Sandoz [SZ] ^a Somac [NQ]

■ RABEPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

rabeprazole sodium 10 mg enteric tablet, 28

8507R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.52	15.77	^a APO-Rabeprazole [TX] ^a Parzol 10 [ZP] ^a Rabeprazole-DRLA [RZ] ^b 5.01	^a Parbezol [RW] ^a Rabeprazole AN [EA] ^a Rabeprazole Sandoz [SZ]
				19.53	15.77	^a Pariet [JC]	

■ RABEPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

Authority required (STREAMLINED)**8780**

Scleroderma oesophagus

rabeprazole sodium 20 mg enteric tablet, 30

8508T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.52	15.77	^a APO-Rabeprazole [TX]	^a Chem mart Rabeprazole [CH]
						^a Parbezol [RW]	^a Parzol 20 [ZP]
						^a Rabeprazole AN [EA]	^a Rabeprazole-DRLA [RZ]
						^a Rabeprazole Sandoz [SZ]	^a Rabeprazole SUN [RN]
						^a Terry White Chemists Rabeprazole [TW]	^a Zabep [AL]
			^B 5.01	19.53	15.77	^a Pariet [JC]	

■ RABEPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

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

Authority required (STREAMLINED)**8776**

Gastro-oesophageal reflux disease

Clinical criteria:

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

rabeprazole sodium 20 mg enteric tablet, 30

11670F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.52	15.77	^a APO-Rabeprazole [TX]	^a Chem mart Rabeprazole [CH]
						^a Parbezol [RW]	^a Parzol 20 [ZP]
						^a Rabeprazole AN [EA]	^a Rabeprazole-DRLA [RZ]
						^a Rabeprazole Sandoz [SZ]	^a Rabeprazole SUN [RN]
						^a Terry White Chemists Rabeprazole [TW]	^a Zabep [AL]
			^B 5.01	19.53	15.77	^a Pariet [JC]	

■ RABEPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

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

Authority required (STREAMLINED)**8775**

Peptic ulcer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

Authority required (STREAMLINED)**8774**

Gastro-oesophageal reflux disease

Clinical criteria:

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

rabeprazole sodium 20 mg enteric tablet, 30

8509W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	14.52	15.77	^a APO-Rabeprazole [TX]	^a Chem mart Rabeprazole [CH]
						^a Parbezol [RW]	^a Parzol 20 [ZP]
						^a Rabeprazole AN [EA]	^a Rabeprazole-DRLA [RZ]

^a Rabeprazole Sandoz [SZ]	^a Rabeprazole SUN [RN]
^a Terry White Chemists Rabeprazole [TW]	^a Zabep [AL]
^a Pariet [JC]	

^B5.01 19.53 15.77

Combinations for eradication of *Helicobacter pylori*

■ ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXICILLIN

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

Restricted benefit

Eradication of *Helicobacter pylori*

Clinical criteria:

- The condition must be associated with peptic ulcer disease.

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

10759G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	36.91	38.16	^a ESOMEPRAZOLE SANDOZ Hp7 [SZ]

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

8738X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	^B 3.58	40.49	38.16	^a Nexium Hp7 [AP]

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

■ SUCRALFATE

sucralfate 1 g tablet, 120

2055E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	27.07	28.32	Carafate [AS]

■ DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, tertiary amines

■ ATROPINE SULFATE

atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules

5022H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	23.15	24.40	Pfizer Australia Pty Ltd [PF]

■ ATROPINE SULFATE

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.

atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules

1089H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	23.15	24.40	Pfizer Australia Pty Ltd [PF]

PROPULSIVES

Propulsives

■ DOMPERIDONE

domperidone 10 mg tablet, 25

1347X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	13.22	14.47	Motilium [JC]

■ METOCLOPRAMIDE

metoclopramide hydrochloride 10 mg tablet, 25

1207M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	12.61	13.86	^a APO-Metoclopramide [TX]	^a EMEXLON [RW]
						^a Metoclopramide AN [EA]	^a Pramin [AF]
			^B 1.91	14.52	13.86	^a Maxolon [IL]	

metoclopramide hydrochloride 10 mg tablet, 25

5151D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.61	13.86	^a APO-Metoclopramide [TX]	^a EMEXLON [RW]
						^a Metoclopramide AN [EA]	^a Pramin [AF]
			^b 1.91	14.52	13.86	^a Maxolon [IL]	

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

1206L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	..	..	17.19	18.44	Maxolon [IL]

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

5153F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	17.19	18.44	Maxolon [IL]

ANTIEMETICS AND ANTINAUSEANTS**ANTIEMETICS AND ANTINAUSEANTS***Serotonin (5HT₃) antagonists***■ GRANISETRON****Restricted benefit**

Nausea and vomiting

Clinical criteria:

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

granisetron 3 mg/3 mL injection, 3 mL ampoule

8729K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	13.54	14.79	^a Granisetron-AFT [AE]	^a Granisetron Kabi [PK]
						^a Kytril [IX]	

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

Nausea and vomiting

Clinical criteria:

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

granisetron 3 mg/3 mL injection, 3 mL ampoule

8730L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	13.54	14.79	^a Granisetron-AFT [AE]	^a Granisetron Kabi [PK]
						^a Kytril [IX]	

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

Nausea and vomiting

Clinical criteria:

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

granisetron 2 mg tablet, 5

8873B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	56.05	40.30	Kytril [IX]

■ GRANISETRON**Restricted benefit**

Nausea and vomiting

Clinical criteria:

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

granisetron 2 mg tablet, 1

8728J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*29.31	30.56	Kytril [IX]

■ NETUPITANT + PALONOSETRON**Note** No increase in the maximum number of repeats may be authorised.**Note** No increase in the maximum quantity or number of units may be authorised.

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

Authority required (STREAMLINED)

5991

Nausea and vomiting

Clinical criteria:

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

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

Authority required (STREAMLINED)

5994

Nausea and vomiting

Clinical criteria:

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

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

Authority required (STREAMLINED)

6937

Nausea and vomiting

Clinical criteria:

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

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

Authority required (STREAMLINED)

6879

Nausea and vomiting

Clinical criteria:

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

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

netupitant 300 mg + palonosetron 500 microgram capsule, 1

10731T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	115.95	40.30	Akynzeo [MF]

▪ **ONDANSETRON**

Authority required (STREAMLINED)

4102

Nausea and vomiting

Clinical criteria:

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

ondansetron 8 mg tablet, 10

1595Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	25.87	27.12	^a APO-Ondansetron [TX] ^a Ondansetron APOTEX [GX] ^a Ondansetron Mylan Tablets [AF] ^a Onsetron 8 [ZP]	^a Ondansetron AN [EA] ^a Ondansetron-DRLA [RZ] ^a Ondansetron SZ [HX] ^a Zofran [AS]

ondansetron 4 mg/5 mL oral liquid, 50 mL

8233H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	98.33	40.30	Zofran syrup 50 mL [AS]

ondansetron 4 mg tablet, 10

1594X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	20.65	21.90	^a APO-Ondansetron [TX] ^a Ondansetron APOTEX [GX] ^a Ondansetron Mylan Tablets [AF] ^a Onsetron 4 [ZP]	^a Ondansetron AN [EA] ^a Ondansetron-DRLA [RZ] ^a Ondansetron SZ [HX] ^a Zofran [AS]

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

Nausea and vomiting

Clinical criteria:

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

ondansetron 4 mg/2 mL injection, 2 mL ampoule

1596B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	11.82	13.07	^a Ondansetron Alphapharm [AF]	^a Onsetron [ZP]

ondansetron 8 mg/4 mL injection, 4 mL ampoule

1597C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.03	13.28	^a Ondansetron Alphapharm [AF]	^a Onsetron [ZP]

■ ONDANSETRON**Restricted benefit**

Nausea and vomiting

Clinical criteria:

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

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

ondansetron 8 mg tablet, 4

8225X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.23	18.48	^a APO-Ondansetron [TX] ^a Ondansetron APOTEX [GX] ^a Ondansetron Mylan Tablets [AF] ^a Onsetron 8 [ZP]	^a Ondansetron AN [EA] ^a Ondansetron-DRLA [RZ] ^a Ondansetron SZ [HX] ^a Zofran [AS]

ondansetron 4 mg tablet, 4

8224W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.15	16.40	^a APO-Ondansetron [TX] ^a Ondansetron APOTEX [GX] ^a Ondansetron Mylan Tablets [AF] ^a Onsetron 4 [ZP]	^a Ondansetron AN [EA] ^a Ondansetron-DRLA [RZ] ^a Ondansetron SZ [HX] ^a Zofran [AS]

■ ONDANSETRON**Restricted benefit**

Nausea and vomiting

Clinical criteria:

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

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

ondansetron 4 mg/2 mL injection, 2 mL ampoule

8226Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	11.82	13.07	^a Ondansetron Alphapharm [AF]	^a Onsetron [ZP]

ondansetron 8 mg/4 mL injection, 4 mL ampoule

8227B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.03	13.28	^a Ondansetron Alphapharm [AF]	^a Onsetron [ZP]

■ ONDANSETRON**Restricted benefit**

Nausea and vomiting

Clinical criteria:

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

ondansetron 4 mg/5 mL oral liquid, 50 mL

8441X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	98.33	40.30	Zofran syrup 50 mL [AS]

■ ONDANSETRON

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

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

Restricted benefit

Nausea and vomiting

Clinical criteria:

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

ondansetron 4 mg orally disintegrating tablet, 4

5470X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.15	16.40	^a Ondansetron AN ODT [EA] ^a Ondansetron ODT-DRLA [RZ] ^a Ondansetron SZ ODT [HX]	^a Ondansetron Mylan ODT [AF] ^a Ondansetron ODT GH [GQ]

ondansetron 8 mg wafer, 4

8411Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	^B 2.45	19.68	18.48	^a Zofran Zydis [AS]

ondansetron 4 mg wafer, 4

8410P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	^B 2.45	17.60	16.40	^a Zofran Zydis [AS]

ondansetron 8 mg orally disintegrating tablet, 4

5471Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.23	18.48	^a Ondansetron AN ODT [EA] ^a Ondansetron ODT-DRLA [RZ] ^a Ondansetron SZ ODT [HX]	^a Ondansetron Mylan ODT [AF] ^a Ondansetron ODT GH [GQ]

■ ONDANSETRON

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

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

Authority required (STREAMLINED)

5777

Nausea and vomiting

Clinical criteria:

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

ondansetron 8 mg orally disintegrating tablet, 10

5473C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	25.87	27.12	^a Ondansetron AN ODT [EA] ^a Ondansetron ODT-DRLA [RZ] ^a Ondansetron SZ ODT [HX]	^a Ondansetron Mylan ODT [AF] ^a Ondansetron ODT GH [GQ] ^a Zilfajim ODT 8 [DO]

ondansetron 8 mg wafer, 10

8413T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	^B 2.45	28.32	27.12	^a Zofran Zydis [AS]

ondansetron 4 mg wafer, 10

8412R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	^B 2.45	23.10	21.90	^a Zofran Zydis [AS]

ondansetron 4 mg orally disintegrating tablet, 10

5472B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	20.65	21.90	^a Ondansetron AN ODT [EA] ^a Ondansetron ODT-DRLA [RZ]	^a Ondansetron Mylan ODT [AF] ^a Ondansetron ODT GH [GQ]

■ PALONOSETRON

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

Note This drug is not PBS-subsidised for administration with oral 5-HT₃ antagonists.

Restricted benefit

Nausea and vomiting

Clinical criteria:

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

palonosetron 250 microgram/5 mL injection, 5 mL vial

5295Q

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	..	..	46.57	40.30	Aloxi [MF]

NP

■ TROPISETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

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

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

tropisetron 5 mg/5 mL injection, 5 mL ampoule

2746M

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	..	..	16.39	17.64	Tropisetron-AFT [AE]

NP

Other antiemetics

■ FOSAPREPITANT

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

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

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

Authority required (STREAMLINED)

6886

Nausea and vomiting

Clinical criteria:

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

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

Authority required (STREAMLINED)

6891

Nausea and vomiting

Clinical criteria:

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

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

Authority required (STREAMLINED)

6887

Nausea and vomiting

Clinical criteria:

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

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

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

Authority required (STREAMLINED)**6852**

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin. No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

fosaprepitant 150 mg injection, 1 vial

11107N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	115.95	40.30	Emend IV [MK]

■ PROCHLORPERAZINE

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

prochlorperazine mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules

5206B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	21.16	22.41	Stemetil [SW]

prochlorperazine maleate 5 mg tablet, 25

5205Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.45	13.70	^a APO-Prochlorperazine [TX] ^a Prochlorperazine AN [EA] ^a Stemizine [AV]	^a ProCalm [RW] ^a Prochlorperazine GH [GQ]
			^B 3.00	15.45	13.70	^a Stemetil [SW]	

■ PROCHLORPERAZINE

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

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

prochlorperazine mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules

2369Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	21.16	22.41	Stemetil [SW]

prochlorperazine maleate 5 mg tablet, 25

2893G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.45	13.70	^a APO-Prochlorperazine [TX] ^a Prochlorperazine AN [EA] ^a Stemizine [AV]	^a ProCalm [RW] ^a Prochlorperazine GH [GQ]
			^B 3.00	15.45	13.70	^a Stemetil [SW]	

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

3374N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*35.07	36.32	Hospira Pty Limited [PF]

■ BILE AND LIVER THERAPY**BILE THERAPY***Bile acids and derivatives***■ URSODEOXYCHOLIC ACID**

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

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.

Authority required (STREAMLINED)**9032**

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

ursodeoxycholic acid 250 mg capsule, 100

8448P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*221.35	40.30	^a APO-Ursodeoxycholic acid [TX]	^a Ursodox GH [GQ]
						^a Ursofalk [OA]	^a Ursosan [BZ]

ursodeoxycholic acid 500 mg tablet, 100

11180K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	288.96	40.30	Ursofalk [OA]

■ DRUGS FOR CONSTIPATION

DRUGS FOR CONSTIPATION

Contact laxatives

■ BISACODYL

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

bisacodyl 5 mg enteric tablet, 200

1259G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.47	18.72	Lax-Tab [AE]

■ BISACODYL

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

Restricted benefit

Constipation

Clinical criteria:

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

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Constipation

Clinical criteria:

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

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Terminal malignant neoplasia

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Anorectal congenital abnormalities

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Megacolon

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

bisacodyl 10 mg suppository, 12

1258F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	4	..	*21.82	23.07	Petrus Bisacodyl Suppositories [PP]

bisacodyl 10 mg suppository, 10

1260H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*24.10	25.35	^a Petrus Bisacodyl Suppositories [PP]
			^B 1.29	*25.39	25.35	^a Dulcolax [VZ]

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

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

rhhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g

1104D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	25.58	26.83	Normacol Plus [NE]

Osmotically acting laxatives**▪ MACROGOL-3350****Restricted benefit**

Constipation

Clinical criteria:

- Patient must have malignant neoplasia.

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

Restricted benefit

Chronic constipation

Clinical criteria:

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

Restricted benefit

Faecal impaction

Clinical criteria:

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

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

3416T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	19.05	20.30	OsmoLax [KY]

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

Constipation

Clinical criteria:

- Patient must have malignant neoplasia.

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

Restricted benefit

Chronic constipation

Clinical criteria:

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

Restricted benefit

Faecal impaction

Clinical criteria:

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

macrogol-3350 13.125 g/25 mL + sodium chloride 350.7 mg/25 mL + sodium bicarbonate 178.5 mg/25 mL + potassium chloride 46.6 mg/25 mL oral liquid, 500 mL

10126Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*21.57	22.82	Movicol Liquid [NE]

macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets

8612G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	19.05	20.30	^a APO-MACROGOL plus ELECTROLYTES [TX] ^a LaxaCon [EA] ^a Macrovic [RF] ^a Movicol [NE]	^a Chemists' Own Macrogol with Electrolytes [RW] ^a lax-sachets [AE] ^a Molaxole [GO]

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

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

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

1263L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	38.89	40.14	Bisalax [AS]

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

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

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

2091C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*29.75	31.00	Micolette [AE]

▪ ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS**INTESTINAL ANTIINFECTIVES***Antibiotics***▪ NYSTATIN****nystatin 500 000 units tablet, 50**

1696G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	20.65	21.90	Nilstat [QA]

nystatin 500 000 units tablet, 50

3342X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	20.65	21.90	Nilstat [QA]

nystatin 500 000 units capsule, 50

1699K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	20.65	21.90	Nilstat [QA]

nystatin 500 000 units capsule, 50

3345C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	20.65	21.90	Nilstat [QA]

■ RIFAXIMIN

Note No 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

Prevention of hepatic encephalopathy

Treatment criteria:

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

Clinical criteria:

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

rifaximin 550 mg tablet, 56

10001J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	466.87	40.30	Xifaxan [NE]

■ VANCOMYCIN

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

Authority required

Antibiotic associated pseudomembranous colitis

Clinical criteria:

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

Authority required

Antibiotic associated pseudomembranous colitis

Clinical criteria:

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

vancomycin 125 mg capsule, 20

3113W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*220.29	40.30	Vancocin [AS]

vancomycin 250 mg capsule, 20

3114X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*435.35	40.30	Vancocin [AS]

ELECTROLYTES WITH CARBOHYDRATES

Oral rehydration salt formulations

■ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID

Restricted benefit

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

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

3196F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	..	..	16.29	17.54	^a O.R.S. [AS]	^a restore O.R.S. [EA]

NP

■ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID

Authority required

Rehydration in intestinal failure

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

11049M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	30	..	..	*155.89	40.30	restore O.R.S. [EA]

ANTIPROPULSIVES

Antipropulsives

■ DIPHENOXYLATE + ATROPINE SULFATE

diphenoxylate hydrochloride 2.5 mg + atropine sulfate monohydrate 25 microgram tablet, 20

2501P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	13.26	14.51	^a Lofenoxal [IL]
			^B 1.51	14.77	14.51	^a Lomotil [IM]

NP

■ LOPERAMIDE

Authority required (STREAMLINED)

6364

Diarrhoea

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

loperamide hydrochloride 2 mg capsule, 12

1571Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.97	14.22	^a Gastrex [CR]	^a Gastro-Stop [AS]

■ LOPERAMIDE

Authority required

Diarrhoea

loperamide hydrochloride 2 mg capsule, 12

10889D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	..	..	*18.94	20.19	^a Gastrex [CR]	^a Gastro-Stop [AS]

INTESTINAL ANTIINFLAMMATORY AGENTS

Corticosteroids acting locally

■ BUDESONIDE

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.

budesonide 2 mg/application enema, 2 x 14 applications

10034D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	163.29	40.30	Budenofalk [OA]

■ HYDROCORTISONE ACETATE

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.

Restricted benefit

Proctitis

Restricted benefit

Ulcerative colitis

hydrocortisone acetate 10% enema, 21.1 g

1502C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*41.07	40.30	Colifoam [GO]

■ PREDNISOLONE SODIUM PHOSPHATE

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.

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

1920C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	3	..	*198.63	40.30	Predsol [QA]

■ PREDNISOLONE SODIUM PHOSPHATE

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.

Restricted benefit

Proctitis

Restricted benefit

Ulcerative colitis

prednisolone (as sodium phosphate) 5 mg suppository, 10

2554K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*42.25	40.30	Predsol [QA]

Aminosalicylic acid and similar agents**■ BALSALAZIDE****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.

Authority required (STREAMLINED)**7621**

Ulcerative colitis

Clinical criteria:

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

balsalazide sodium 750 mg capsule, 280

11351K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	154.66	40.30	Colazide [PK]

■ MESALAZINE**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.

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.

mesalazine 1 g modified release granules, 100 sachets

8599N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	219.73	40.30	Salofalk [OA]

mesalazine 3 g modified release granules, 30 sachets

10257W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	190.59	40.30	Salofalk [OA]

mesalazine 1.2 g modified release tablet, 60

9353G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*335.69	40.30	Mezavant [ZI]

mesalazine 500 mg modified release granules, 100 sachets

8598M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*234.69	40.30	Salofalk [OA]

mesalazine 1.5 g modified release granules, 60 sachets

9206M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	190.59	40.30	Salofalk [OA]

mesalazine 800 mg enteric tablet, 90

11210B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*295.65	40.30	Asacol [EU]

mesalazine 4 g modified release granules, 30 sachets

10254Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	247.19	40.30	Pentasa [FP]

■ MESALAZINE**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.

Authority required (STREAMLINED)**4873**

Ulcerative colitis

Clinical criteria:

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

Authority required (STREAMLINED)**4896**

Crohn disease

Clinical criteria:

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

mesalazine 1 g modified release tablet, 60

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3413P	2	5	..	*262.65	40.30	Pentasa [FP]

NP

mesalazine 1 g modified release granules, 120 sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2234N	1	5	..	262.64	40.30	Pentasa [FP]

NP

mesalazine 2 g modified release granules, 60 sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2287J	1	5	..	247.19	40.30	Pentasa [FP]

NP

mesalazine 1 g enteric tablet, 60

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11554D	2	5	..	*247.21	40.30	Salofalk [OA]

NP

mesalazine 500 mg modified release tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2214M	2	5	..	*234.69	40.30	Pentasa [FP]

NP

mesalazine 250 mg enteric tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1611T	1	5	..	75.73	40.30	Mesasal [AS]

NP

mesalazine 500 mg enteric tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8731M	2	5	..	*234.69	40.30	Salofalk [OA]

NP

■ MESALAZINE**Note** Not for the treatment of Crohn disease**Note** No 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 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.

Restricted benefit

Acute episode of mild to moderate ulcerative proctitis

mesalazine 1 g suppository, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5461K	1	1	..	107.45	40.30	Salofalk [OA]

NP

mesalazine 1 g suppository, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8752P	1	1	..	107.45	40.30	Pentasa [FP]

NP

■ MESALAZINE**Note** Not for the treatment of Crohn disease**Note** No 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 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.

Authority required (STREAMLINED)**4888**

Acute episode of mild to moderate ulcerative colitis

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

8753Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*267.31	40.30	Pentasa [FP]

mesalazine 1 g/application enema, 14 applications

8768L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*267.31	40.30	Salofalk [OA]

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

8617M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*359.51	40.30	Salofalk [OA]

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

8616L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*267.31	40.30	Salofalk [OA]

■ OLSALAZINE**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.

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.

olsalazine sodium 500 mg tablet, 100

8086N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	83.01	40.30	Dipentum [IX]

olsalazine sodium 250 mg capsule, 100

1728Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	52.09	40.30	Dipentum [IX]

■ SULFASALAZINE**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.

sulfasalazine 500 mg enteric tablet, 100

2096H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*54.83	40.30	^a Pyralin EN [FZ]
			^B 4.00	*58.83	40.30	^a Salazopyrin-EN [PF]

sulfasalazine 500 mg tablet, 100

2093E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*50.85	40.30	Salazopyrin [PF]

■ SULFASALAZINE**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Restricted benefit**

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

sulfasalazine 500 mg enteric tablet, 100

9209Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	11	..	*54.83	40.30	^a Pyralin EN [FZ]
			^B 4.00	*58.83	40.30	^a Salazopyrin-EN [PF]

sulfasalazine 500 mg tablet, 100

9208P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	11	..	*50.85	40.30	Salazopyrin [PF]

DIGESTIVES, INCL. ENZYMES

DIGESTIVES, INCL. ENZYMES

Enzyme preparations

PANCREATIC EXTRACT

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.

pancreatic extract 10 000 units modified release capsule, 100

8020D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	10	..	*142.39	40.30	Creon 10,000 [GO]

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

5453B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	10	..	*111.43	40.30	Creon Micro [GO]

pancreatic extract 25 000 units modified release capsule, 100

8021E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	10	..	*115.85	40.30	Creon 25,000 [GO]

pancreatic extract 40 000 units modified release capsule, 100

9412J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	10	..	*178.43	40.30	Creon 40,000 [GO]

PANCREATIC EXTRACT

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

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

Restricted benefit

Cystic fibrosis

Clinical criteria:

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

pancreatic extract 10 000 units modified release capsule, 100

9226N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	21	..	*142.39	40.30	Creon 10,000 [GO]

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

5454C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	21	..	*111.43	40.30	Creon Micro [GO]

pancreatic extract 25 000 units modified release capsule, 100

9227P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	21	..	*115.85	40.30	Creon 25,000 [GO]

pancreatic extract 40 000 units modified release capsule, 100

9413K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	21	..	*178.43	40.30	Creon 40,000 [GO]

PANCRELIPASE

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.

pancrelipase 25 000 units capsule, 100

8366H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	10	..	*108.55	40.30	Panzytrat 25000 [TM]

PANCRELIPASE

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

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

Restricted benefit

Cystic fibrosis

Clinical criteria:

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

pancrelipase 25 000 units capsule, 100

9229R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	21	..	*108.55	40.30	Panzytrat 25000 [TM]

DRUGS USED IN DIABETES

INSULINS AND ANALOGUES

Insulins and analogues for injection, fast-acting

INSULIN ASPART

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

8571D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	2	..	*124.39	40.30	NovoRapid [NO]

insulin aspart 100 units/mL fast acting injection, 5 x 3 mL pen devices

11706D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*206.74	40.30	Fiasp FlexTouch [NO]

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

11705C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	2	..	*124.39	40.30	Fiasp [NO]

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

8435Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*206.74	40.30	NovoRapid FlexPen [NF]	NovoRapid Penfill 3 mL [NO]

INSULIN GLULISINE

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

9224L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	2	..	*130.29	40.30	Apidra [SW]

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

1921D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*217.39	40.30	Apidra [AV]	Apidra SoloStar [SW]

INSULIN LISPRO

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

8084L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	2	..	*124.39	40.30	Humalog [LY]

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

8212F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*206.74	40.30	Humalog [LY]	Humalog KwikPen [KP]

insulin lispro 200 units/mL injection, 5 x 3 mL pen devices

11645X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*408.34	40.30	Humalog U200 Kwikpen [LY]

INSULIN NEUTRAL HUMAN

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

1762R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*173.84	40.30	Actrapid Penfill 3 mL [NO]	Humulin R [LY]

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

1531N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	2	..	*105.54	40.30	Actrapid [NO]	Humulin R [LY]

Insulins and analogues for injection, intermediate-acting

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

1533Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	2	..	*105.54	40.30	Humulin NPH [LY]	Protaphane [NO]

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

1761Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*173.84	40.30	Humulin NPH [LY] Protaphane Penfill 3 mL [NO]	Protaphane InnoLet [NI]

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

8609D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*206.74	40.30	NovoMix 30 FlexPen [NF]	NovoMix 30 Penfill 3 mL [NO]

■ **INSULIN DEGLUDEC + INSULIN ASPART****Note** Special Pricing Arrangements apply.**insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL pen devices**

11417X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*372.39	40.30	Ryzodeg Flextouch [NO]

insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL cartridges

11426J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*372.39	40.30	Ryzodeg Penfill [NO]

■ **INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN****insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 1 x 10 mL vial**

1426C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	2	..	*105.54	40.30	Humulin 30/70 [LY]

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

1763T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*173.84	40.30	Humulin 30/70 [LY] Mixtard 30/70 Penfill 3 mL [NO]	Mixtard 30/70 InnoLet [NI]

insulin neutral human 50 units/mL + insulin isophane human 50 units/mL injection, 5 x 3 mL cartridges

2062M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*181.79	40.30	Mixtard 50/50 Penfill 3 mL [NO]

■ **INSULIN LISPRO + INSULIN LISPRO PROTAMINE****insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL cartridges**

8874C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*206.74	40.30	Humalog Mix50 [LY]	Humalog Mix50 KwikPen [KP]

insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL cartridges

8390N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*206.74	40.30	Humalog Mix25 [LY]	Humalog Mix25 KwikPen [KP]

Insulins and analogues for injection, long-acting■ **INSULIN DETEMIR****Note** Special Pricing Arrangements apply.**Restricted benefit**

Type 1 diabetes

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

9040T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*347.99	40.30	Levemir FlexPen [NF]	Levemir Penfill [NO]

■ INSULIN GLARGINE

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

9039R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*240.44	40.30	Lantus [SW]	Lantus SoloStar [AV]

■ INSULIN GLARGINE

Note Special Pricing Arrangements apply.

insulin glargine 300 units/mL injection, 5 x 1.5 mL pen devices

11302W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*547.19	40.30	Toujeo Solostar [SW]	

insulin glargine 300 units/mL injection, 3 x 1.5 mL pen devices

11308E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*330.44	40.30	Toujeo Solostar [SW]	

BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

Biguanides

■ METFORMIN

metformin hydrochloride 500 mg tablet, 100

2430X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.17	15.42	^a APO-Metformin 500 [TX] ^a Diaformin [AF] ^a Glucobete 500 [DO] ^a Metformin generichealth [GQ] ^a Terry White Chemists Metformin [TW]	^a Chem mart Metformin [CH] ^a FORMET 500 [RF] ^a Metformin AN [EA] ^a Metformin Sandoz [SZ]
			^B 4.95	19.12	15.42	^a Diabex [AL]	

metformin hydrochloride 850 mg tablet, 60

1801T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.17	15.42	^a APO-Metformin 850 [TX] ^a Diaformin 850 [AF] ^a Glucobete 850 [DO] ^a Metformin Sandoz [SZ]	^a Chem mart Metformin [CH] ^a FORMET 850 [RF] ^a Metformin AN [EA] ^a Terry White Chemists Metformin [TW]
			^B 4.95	19.12	15.42	^a Diabex 850 [AL]	

metformin hydrochloride 500 mg modified release tablet, 120

9435N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.79	17.04	^a APO-Metformin XR 500 [TX] ^a Chem mart Metformin XR 500 [CH] ^a Metex XR [RW] ^a Terry White Chemists Metformin XR 500 [TW]	^a Blooms the Chemist Metformin XR 500 [IB] ^a Diaformin XR [AF] ^a Metformin XR 500 APOTEX [GX]
			^B 4.95	20.74	17.04	^a Diabex XR [AL]	

metformin hydrochloride 1 g tablet, 90

8607B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.17	17.42	^a APO-Metformin 1000 [TX] ^a Diaformin 1000 [AF] ^a Glucobete 1000 [DO] ^a Metformin generichealth 1000 [GQ] ^a Metformin Sandoz [SZ] ^a Terry White Chemists Metformin 1000 [TW]	^a Chem mart Metformin 1000 [CH] ^a Formet 1000 [RW] ^a Metformin AN [EA] ^a Metformin GH [HQ] ^a Sandoz Metformin [HX]
			^B 4.95	21.12	17.42	^a Diabex 1000 [AL]	

metformin hydrochloride 1 g modified release tablet, 60

3439B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.79	17.04	^a APO-Metformin XR 1000 [TX] ^a Chem mart Metformin XR 1000 [CH]	^a Blooms the Chemist Metformin XR 1000 [IB] ^a Diaformin XR 1000 [AF]

^a METEX XR [RF]^a METEX XR 1000 [RW]^a Terry White Chemists
Metformin XR 1000 [TW]^B4.95 20.74 17.04 ^a Diabex XR 1000 [AL]**Sulfonylureas****■ GLIBENCLAMIDE****Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.**glibenclamide 5 mg tablet, 100**

2939Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.80	17.05	Daonil [SW]

■ GLICLAZIDE**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.**gliclazide 60 mg modified release tablet, 60**

9302N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.72	19.97	^a ARDIX GLICLAZIDE 60mg MR [RX]
			^B 7.62	26.34	19.97	^a Diamicon 60mg MR [SE]

gliclazide 30 mg modified release tablet, 100

8535F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.51	18.76	^a APO-Gliclazide MR [TX]	^a Glyade MR [AF]

gliclazide 80 mg tablet, 100

2449X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.34	18.59	^a APO-Gliclazide [TX] ^a Glyade [AF]	^a GenRx Gliclazide [GX] ^a Nidem [RW]

■ GLIMEPIRIDE**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.**glimepiride 4 mg tablet, 30**

8452W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.38	15.63	^a APO-Glimepiride [TX] ^a Diapride 4 [RW] ^a Glimepiride AN [EA] ^a Glimepiride Sandoz [SZ]	^a Aylide 4 [AF] ^a Dimirel [AV] ^a Glimepiride APOTEX [GX]
			^B 2.19	16.57	15.63	^a Amaryl [SW]	

glimepiride 3 mg tablet, 30

8533D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.83	15.08	^a APO-Glimepiride [TX] ^a Diapride 3 [RW] ^a Glimepiride AN [EA] ^a Glimepiride Sandoz [SZ]	^a Aylide 3 [AF] ^a Dimirel [AV] ^a Glimepiride APOTEX [GX]
			^B 2.19	16.02	15.08	^a Amaryl [SW]	

glimepiride 2 mg tablet, 30

8451T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.33	14.58	^a APO-Glimepiride [TX] ^a Diapride 2 [RW] ^a Glimepiride AN [EA] ^a Glimepiride Sandoz [SZ]	^a Aylide 2 [AF] ^a Dimirel [AV] ^a Glimepiride APOTEX [GX]
			^B 2.18	15.51	14.58	^a Amaryl [SW]	

glimepiride 1 mg tablet, 30

8450R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.45	13.70	^a APO-Glimepiride [TX] ^a Diapride 1 [RW] ^a Glimepiride AN [EA] ^a Glimepiride Sandoz [SZ]	^a Aylide 1 [AF] ^a Dimirel [AV] ^a Glimepiride APOTEX [GX]
			^B 2.23	14.68	13.70	^a Amaryl [SW]	

■ GLIPIZIDE**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.**glipizide 5 mg tablet, 100**

2440K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.27	24.52	^a Melizide [AF]	^a Minidiab [PF]

Combinations of oral blood glucose lowering drugs

■ ALOGLIPTIN + METFORMIN

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

Authority required (STREAMLINED)**4423**

Diabetes mellitus type 2

Clinical criteria:

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; 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 metformin.

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 does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Authority required (STREAMLINED)**4427**

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

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

alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56

10032B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.27	40.30	Nesina Met 12.5/850 [TK]

alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56

10035E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.68	40.30	Nesina Met 12.5/1000 [TK]

alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56

10033C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.27	40.30	Nesina Met 12.5/500 [TK]

■ DAPAGLIFLOZIN + METFORMIN

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

Authority required (STREAMLINED)**7498**

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and a gliptin for this condition; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

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

11270E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	57.06	40.30	Xigduo XR 10/500 [AP]

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

11300R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	59.22	40.30	Xigduo XR 5/1000 [AP]

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

11313K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	57.81	40.30	Xigduo XR 10/1000 [AP]

■ DAPAGLIFLOZIN + METFORMIN

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.

Authority required (STREAMLINED)

5631

Diabetes mellitus type 2

Clinical criteria:

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; 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 metformin.

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 does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

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

Authority required (STREAMLINED)

5739

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Authority required (STREAMLINED)

5798

Diabetes mellitus type 2

Clinical criteria:

- 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 optimal doses of dual oral therapy; 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 despite treatment with optimal doses of dual oral therapy.

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.

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 fixed dose combination.

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

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

Authority required (STREAMLINED)

5657

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
- (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 fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

7492

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

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

10516L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	57.06	40.30	Xigduo XR 10/500 [AP]

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

10510E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.22	40.30	Xigduo XR 5/1000 [AP]

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

10515K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	57.81	40.30	Xigduo XR 10/1000 [AP]

■ EMPAGLIFLOZIN + LINAGLIPTIN

Note This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

Authority required (STREAMLINED)**7524**

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a dipeptidyl peptidase 4 inhibitor (gliptin) or a sodium-glucose co-transporter 2 (SGLT2) inhibitor; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

empagliflozin 25 mg + linagliptin 5 mg tablet, 30

11303X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	84.70	40.30	Glyxambi [BY]

empagliflozin 10 mg + linagliptin 5 mg tablet, 30

11269D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	84.70	40.30	Glyxambi [BY]

■ EMPAGLIFLOZIN + LINAGLIPTIN

Note This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

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.

Authority required (STREAMLINED)**7556**

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

empagliflozin 25 mg + linagliptin 5 mg tablet, 30

11298P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	84.70	40.30	Glyxambi [BY]

empagliflozin 10 mg + linagliptin 5 mg tablet, 30

11310G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	84.70	40.30	Glyxambi [BY]

■ EMPAGLIFLOZIN + METFORMIN**Authority required (STREAMLINED)****5953**

Diabetes mellitus type 2

Clinical criteria:

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; 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 metformin.

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.

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

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

Authority required (STREAMLINED)

7498

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and a gliptin for this condition; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

10650M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	63.64	40.30	Jardiamet 5 mg/500 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60

10639Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	63.64	40.30	Jardiamet 12.5 mg/500 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

10640B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	65.15	40.30	Jardiamet 12.5 mg/1000 mg [BY]

empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60

10649L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	65.15	40.30	Jardiamet 5 mg/1000 mg [BY]

■ EMPAGLIFLOZIN + METFORMIN

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.

Authority required (STREAMLINED)

5966

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Authority required (STREAMLINED)

5798

Diabetes mellitus type 2

Clinical criteria:

- 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 optimal doses of dual oral therapy; 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 despite treatment with optimal doses of dual oral therapy.

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.

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 fixed dose combination.

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

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

Authority required (STREAMLINED)

5657

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
- (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 fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

7492

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

10626G

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	63.64	40.30	Jardiamet 5 mg/500 mg [BY]

NP

empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60

10633P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	63.64	40.30	Jardimet 12.5 mg/500 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

10677Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	65.15	40.30	Jardimet 12.5 mg/1000 mg [BY]

empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60

10627H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	65.15	40.30	Jardimet 5 mg/1000 mg [BY]

■ ERTUGLIFLOZIN + METFORMIN

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), insulin, a glucagon-like peptide-1 analogue, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

Authority required (STREAMLINED)**7498**

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and a gliptin for this condition; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

ertugliflozin 7.5 mg + metformin hydrochloride 500 mg tablet, 56

11562M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	60.17	40.30	Segluromet 7.5/500 [MK]

ertugliflozin 7.5 mg + metformin hydrochloride 1 g tablet, 56

11569X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	61.57	40.30	Segluromet 7.5/1000 [MK]

ertugliflozin 2.5 mg + metformin hydrochloride 1 g tablet, 56

11564P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	61.57	40.30	Segluromet 2.5/1000 [MK]

ertugliflozin 2.5 mg + metformin hydrochloride 500 mg tablet, 56

11584Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	60.17	40.30	Segluromet 2.5/500 [MK]

■ ERTUGLIFLOZIN + METFORMIN**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.

Authority required (STREAMLINED)**5631**

Diabetes mellitus type 2

Clinical criteria:

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; 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 metformin.

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 does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

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

Authority required (STREAMLINED)

8249

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Authority required (STREAMLINED)

7492

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), insulin, a glucagon-like peptide-1 analogue, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

ertugliflozin 7.5 mg + metformin hydrochloride 500 mg tablet, 56

11568W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	60.17	40.30	Segluromet 7.5/500 [MK]

ertugliflozin 7.5 mg + metformin hydrochloride 1 g tablet, 56

11563N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.57	40.30	Segluromet 7.5/1000 [MK]

ertugliflozin 2.5 mg + metformin hydrochloride 1 g tablet, 56

11581M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.57	40.30	Segluromet 2.5/1000 [MK]

ertugliflozin 2.5 mg + metformin hydrochloride 500 mg tablet, 56

11575F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	60.17	40.30	Segluromet 2.5/500 [MK]

■ ERTUGLIFLOZIN + SITAGLIPTIN

Note This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

Authority required (STREAMLINED)

7524

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a dipeptidyl peptidase 4 inhibitor (gliptin) or a sodium-glucose co-transporter 2 (SGLT2) inhibitor; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

ertugliflozin 5 mg + sitagliptin 100 mg tablet, 28

11561L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	76.48	40.30	Steglujan 5/100 [MK]

ertugliflozin 15 mg + sitagliptin 100 mg tablet, 28

11583P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	76.48	40.30	Steglujan 15/100 [MK]

■ ERTUGLIFLOZIN + SITAGLIPTIN

Note This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

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.

Authority required (STREAMLINED)

7556

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

ertugliflozin 5 mg + sitagliptin 100 mg tablet, 28

11579K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	76.48	40.30	Steglujan 5/100 [MK]

ertugliflozin 15 mg + sitagliptin 100 mg tablet, 28

11578J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	76.48	40.30	Steglujan 15/100 [MK]

■ LINAGLIPTIN + METFORMIN

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

Authority required (STREAMLINED)

7507

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

11274J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	61.62	40.30	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

11294K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	62.69	40.30	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60

11282T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	63.13	40.30	Trajentamet [BY]

■ LINAGLIPTIN + METFORMIN

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.

Authority required (STREAMLINED)

6333

Diabetes mellitus type 2

Clinical criteria:

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; 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 metformin.

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 does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

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

Authority required (STREAMLINED)

6336

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

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

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

Authority required (STREAMLINED)

6344

Diabetes mellitus type 2

Clinical criteria:

- 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 optimal doses of dual oral therapy; 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 optimal doses of dual oral therapy.

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.

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 fixed dose combination.

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

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

Authority required (STREAMLINED)

6443

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
- (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 fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

7530

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

10038H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.62	40.30	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

10045Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	62.69	40.30	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60

10044P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	63.13	40.30	Trajentamet [BY]

■ METFORMIN + GLIBENCLAMIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

metformin hydrochloride 250 mg + glibenclamide 1.25 mg tablet, 90

8838E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.11	18.36	Glucovance 250mg/1.25mg [AL]

metformin hydrochloride 500 mg + glibenclamide 2.5 mg tablet, 90

8810Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.82	19.07	Glucovance 500mg/2.5mg [AL]

metformin hydrochloride 500 mg + glibenclamide 5 mg tablet, 90

8811R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.81	20.06	Glucovance 500mg/5mg [AL]

■ SAXAGLIPTIN + DAPAGLIFLOZIN

Note This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

Authority required (STREAMLINED)**7524**

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a dipeptidyl peptidase 4 inhibitor (gliptin) or a sodium-glucose co-transporter 2 (SGLT2) inhibitor; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28

11286B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	78.08	40.30	Qtern 5/10 [AP]

■ SAXAGLIPTIN + DAPAGLIFLOZIN

Note This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

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.

Authority required (STREAMLINED)**7556**

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28

11305B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	78.08	40.30	Qtern 5/10 [AP]

■ SAXAGLIPTIN + METFORMIN

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

Authority required (STREAMLINED)**7507**

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28

11312J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	57.52	40.30	Kombiglyze XR 5/500 [AP]

saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28

11299Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	58.27	40.30	Kombiglyze XR 5/1000 [AP]

saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56

11285Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	59.68	40.30	Kombiglyze XR 2.5/1000 [AP]

■ SAXAGLIPTIN + METFORMIN**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.

Authority required (STREAMLINED)**6333**

Diabetes mellitus type 2

Clinical criteria:

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; 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 metformin.

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 does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

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

Authority required (STREAMLINED)

6335

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

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

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

Authority required (STREAMLINED)

6344

Diabetes mellitus type 2

Clinical criteria:

- 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 optimal doses of dual oral therapy; 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 optimal doses of dual oral therapy.

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.

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 fixed dose combination.

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

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

Authority required (STREAMLINED)

7530

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28

10055F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	57.52	40.30	Kombiglyze XR 5/500 [AP]

saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28

10051B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.27	40.30	Kombiglyze XR 5/1000 [AP]

saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56

10048W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.68	40.30	Kombiglyze XR 2.5/1000 [AP]

■ SITAGLIPTIN + METFORMIN

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

Authority required (STREAMLINED)

7507

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56

11582N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	54.75	40.30	Janumet [MK]

sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56

11580L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	55.15	40.30	Janumet XR [MK]

sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56

11574E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	55.15	40.30	Janumet [MK]

sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28

11566R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	53.75	40.30	Janumet XR [MK]

sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56

11586T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	53.75	40.30	Janumet [MK]

■ SITAGLIPTIN + METFORMIN

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.

Authority required (STREAMLINED)

6333

Diabetes mellitus type 2

Clinical criteria:

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; 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 metformin.

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 does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

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

Authority required (STREAMLINED)

6334

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

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

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

Authority required (STREAMLINED)

6344

Diabetes mellitus type 2

Clinical criteria:

- 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 optimal doses of dual oral therapy; **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 optimal doses of dual oral therapy.

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.

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 fixed dose combination.

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

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

Authority required (STREAMLINED)

6443

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
- (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 fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)**7530**

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9450J	1	5	..	54.75	40.30	Janumet [MK]

NP

sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10090C	1	5	..	55.15	40.30	Janumet XR [MK]

NP

sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9451K	1	5	..	55.15	40.30	Janumet [MK]

NP

sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10089B	1	5	..	53.75	40.30	Janumet XR [MK]

NP

sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9449H	1	5	..	53.75	40.30	Janumet [MK]

NP

■ VILDAGLIPTIN + METFORMIN

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

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.

Authority required (STREAMLINED)**6333**

Diabetes mellitus type 2

Clinical criteria:

- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; 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 metformin.

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 does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Authority required (STREAMLINED)**6357**

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

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

Authority required (STREAMLINED)**6344**

Diabetes mellitus type 2

Clinical criteria:

- 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 optimal doses of dual oral therapy; **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 optimal doses of dual oral therapy.

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.

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 fixed dose combination.

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

Authority required (STREAMLINED)**6443**

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
- (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.

vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60

5476F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	60.71	40.30	Galvumet 50/1000 [NV]

vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60

5475E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	60.27	40.30	Galvumet 50/850 [NV]

vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60

5474D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.20	40.30	Galvumet 50/500 [NV]

Alpha glucosidase inhibitors**■ ACARBOSE****acarbose 100 mg tablet, 90**

8189B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	39.10	40.30	^a Acarbose Mylan [AF]	^a GLYBOSAY [RW]

			^B 2.69	41.79	40.30	^a Glucobay 100 [BN]	
NP	Acarbose 50 mg tablet, 90						
8188Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	30.98	32.23	^a Acarbose Mylan [AF]	^a GLYBOSAY [RW]
			^B 2.69	33.67	32.23	^a Glucobay 50 [BN]	

Thiazolidinediones■ **PIOGLITAZONE**

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)**4363**

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**
- 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.

Authority required (STREAMLINED)**4388**

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
- (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.

Authority required (STREAMLINED)**4364**

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.

pioglitazone 15 mg tablet, 28

8694N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.24	20.49	^a Acpio 15 [RF] ^a Actos [TK] ^a Pioglitazone AN [EA] ^a Vexazone [AF]	^a Actaze [RW] ^a APOTEX-Pioglitazone [TX] ^a Pioglitazone Sandoz [SZ]

pioglitazone 45 mg tablet, 28

8696Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	27.01	28.26	^a Acpio 45 [RF] ^a Actos [TK] ^a Pioglitazone AN [EA] ^a Vexazone [AF]	^a Actaze [RW] ^a APOTEX-Pioglitazone [TX] ^a Pioglitazone Sandoz [SZ]

pioglitazone 30 mg tablet, 28

8695P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.43	24.68	^a Acpio 30 [RF] ^a Actos [TK] ^a Pioglitazone AN [EA] ^a Vexazone [AF]	^a Actaze [RW] ^a APOTEX-Pioglitazone [TX] ^a Pioglitazone Sandoz [SZ]

Dipeptidyl peptidase 4 (DPP-4) inhibitors

■ ALOGLIPTIN

Note Alogliptin 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 glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

4349

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.

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 alogliptin.

alogliptin 6.25 mg tablet, 28

2944Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	56.77	40.30	Nesina [TK]

alogliptin 12.5 mg tablet, 28

2933J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	56.77	40.30	Nesina [TK]

alogliptin 25 mg tablet, 28

2986E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	56.77	40.30	Nesina [TK]

■ LINAGLIPTIN

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

Authority required (STREAMLINED)**7541**

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

linagliptin 5 mg tablet, 30

11280Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	60.00	40.30	Trajenta [BY]

■ LINAGLIPTIN**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.

Authority required (STREAMLINED)**6346**

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.

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 This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)**6363**

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 optimal doses of dual oral therapy; **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 optimal doses of dual oral therapy.

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.

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 This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

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

Authority required (STREAMLINED)**6376**

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
- (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 thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)**7505**

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

linagliptin 5 mg tablet, 30

3387G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	60.00	40.30	Trajenta [BY]

■ SAXAGLIPTIN

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

Authority required (STREAMLINED)**7541**

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

saxagliptin 5 mg tablet, 28

11311H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	56.77	40.30	Onglyza [AP]

saxagliptin 2.5 mg tablet, 28

11292H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	56.77	40.30	Onglyza [AP]

■ SAXAGLIPTIN**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.

Authority required (STREAMLINED)**6346**

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.

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 This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

6363

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 optimal doses of dual oral therapy; **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 optimal doses of dual oral therapy.

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.

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 This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

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

Authority required (STREAMLINED)

7505

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or
 • a gliptin with a glitazone; or
 • an SGLT2 inhibitor with a glitazone.

saxagliptin 5 mg tablet, 28

8983T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	56.77	40.30	Onglyza [AP]

saxagliptin 2.5 mg tablet, 28

10128C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	56.77	40.30	Onglyza [AP]

■ SITAGLIPTIN

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or
 • a gliptin with a glitazone; or
 • an SGLT2 inhibitor with a glitazone.

Authority required (STREAMLINED)

7541

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

sitagliptin 50 mg tablet, 28

11573D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	52.24	40.30	Januvia [MK]

sitagliptin 100 mg tablet, 28

11576G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	52.24	40.30	Januvia [MK]

sitagliptin 25 mg tablet, 28

11572C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	52.24	40.30	Januvia [MK]

■ SITAGLIPTIN**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.

Authority required (STREAMLINED)**6346**

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.

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 This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)**6363**

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 optimal doses of dual oral therapy; 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 optimal doses of dual oral therapy.

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.

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 This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

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

Authority required (STREAMLINED)

6376

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
- (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 thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

7505

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

sitagliptin 50 mg tablet, 28

9181F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	52.24	40.30	Januvia [MK]

sitagliptin 100 mg tablet, 28

9182G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	52.24	40.30	Januvia [MK]

sitagliptin 25 mg tablet, 28

9180E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	52.24	40.30	Januvia [MK]

■ VILDAGLIPTIN

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

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.

Authority required (STREAMLINED)**6346**

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. 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.

Authority required (STREAMLINED)**6363**

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 optimal doses of dual oral therapy; 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 optimal doses of dual oral therapy.

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.

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

Authority required (STREAMLINED)**6376**

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
- (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.

vildagliptin 50 mg tablet, 60

3415R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	60.00	40.30	Galvus [NV]

Glucagon-like peptide-1 (GLP-1) analogues

■ DULAGLUTIDE

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 SGLT2 inhibitor, an insulin or a sulfonylurea as dual therapy.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7645

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be in combination with metformin, **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**
- 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 metformin; 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 metformin.

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.

Authority required (STREAMLINED)

5478

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.

dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices

11364D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	131.30	40.30	Trulicity [LY]

■ EXENATIDE

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.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6519

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**
- 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.

Authority required (STREAMLINED)

6505

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.

exenatide 2 mg/dose injection: modified release, 4 injection devices

10888C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	131.30	40.30	Bydureon [AP]

■ EXENATIDE

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

Authority required (STREAMLINED)

5500

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**
- 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.

Authority required (STREAMLINED)**5478**

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.

Authority required (STREAMLINED)**5469**

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be in combination with insulin, **AND**
- The treatment must be in combination with metformin unless contraindicated or not tolerated, **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
- (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.

exenatide 10 microgram/0.04 mL injection, 2.4 mL pen device

3424F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	89.93	40.30	Byetta 10 microgram [AP]

exenatide 5 microgram/0.02 mL injection, 1.2 mL pen device

3423E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	66.39	40.30	Byetta 5 microgram [AP]

Sodium-glucose co-transporter 2 (SGLT2) inhibitors**■ DAPAGLIFLOZIN**

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

Authority required (STREAMLINED)**7528**

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a gliptin; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

dapagliflozin 10 mg tablet, 28

11291G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	56.31	40.30	Forxiga [AP]

■ DAPAGLIFLOZIN**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.

Authority required (STREAMLINED)**7506**

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.
- 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 triple oral therapy with a gliptin and 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 This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

4991

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
- (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 thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

5629

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 optimal doses of dual oral therapy; **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 despite treatment with optimal doses of dual oral therapy.

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.

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 This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

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

Authority required (STREAMLINED)

7495

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

dapagliflozin 10 mg tablet, 28

10011X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	56.31	40.30	Forxiga [AP]

■ EMPAGLIFLOZIN

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

Authority required (STREAMLINED)

7528

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a gliptin; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

empagliflozin 25 mg tablet, 30

11281R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	62.03	40.30	Jardiance [BY]

empagliflozin 10 mg tablet, 30

11314L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	62.03	40.30	Jardiance [BY]

■ EMPAGLIFLOZIN

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.

Authority required (STREAMLINED)

7506

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.

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 triple oral therapy with a gliptin and 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 This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

4991

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
(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 thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

5629

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 optimal doses of dual oral therapy; **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 despite treatment with optimal doses of dual oral therapy.

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.

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 This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

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

Authority required (STREAMLINED)

7495

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**

- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

empagliflozin 25 mg tablet, 30

10202Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	62.03	40.30	Jardiance [BY]

empagliflozin 10 mg tablet, 30

10206E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	62.03	40.30	Jardiance [BY]

■ ERTUGLIFLOZIN

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), insulin or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

Authority required (STREAMLINED)

7528

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a gliptin; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

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

- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

ertugliflozin 5 mg tablet, 28

11577H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	58.66	40.30	Steglatro 5 [MK]

ertugliflozin 15 mg tablet, 28

11570Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	58.66	40.30	Steglatro 15 [MK]

■ ERTUGLIFLOZIN

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.

Authority required (STREAMLINED)

7506

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.

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

Authority required (STREAMLINED)

7495

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), insulin or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

ertugliflozin 5 mg tablet, 28

11585R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.66	40.30	Steglatro 5 [MK]

ertugliflozin 15 mg tablet, 28

11571B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.66	40.30	Steglatro 15 [MK]

■ VITAMINS

VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO

Vitamin D and analogues

■ CALCITRIOL

Authority required (STREAMLINED)

5401

Hypocalcaemia

Clinical criteria:

- The condition must be due to renal disease.

Authority required (STREAMLINED)

5255

Hypoparathyroidism

Authority required (STREAMLINED)

5089

Hypophosphataemic rickets

Authority required (STREAMLINED)

5114

Vitamin D-resistant rickets

Authority required (STREAMLINED)

5402

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

calcitriol 0.25 microgram capsule, 100

2502Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	27.60	28.85	^a APO-Calcitriol [TX] ^a Calcitriol AN [EA] ^a Kosteo [RW]	^a Calciprox [ER] ^a CALITROL [ED] ^a Sical [AF]
			^b 2.29	29.89	28.85	^a Rocaltrol [RO]	

VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12*Vitamin B1, plain***■ THIAMINE****Authority required (STREAMLINED)****5139**

Thiamine deficiency

Clinical criteria:

- The treatment must be for prophylaxis.

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

thiamine hydrochloride 100 mg tablet, 100

1070H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	15.37	16.62	Betavit [PP]

■ MINERAL SUPPLEMENTS**CALCIUM***Calcium***■ CALCIUM****Authority required (STREAMLINED)****4586**

Hyperphosphataemia

Clinical criteria:

- The condition must be associated with chronic renal failure.

CALCIUM Tablet 600 mg (as carbonate), 240

3117C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	22.62	23.87	Calci-Tab 600 [AE]

■ CALCIUM

Note Pharmaceutical benefits that have the form calcium 500 mg tablet (chewable), 60 and pharmaceutical benefits that have the form calcium 500 mg tablet (chewable), 120 are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**4586**

Hyperphosphataemia

Clinical criteria:

- The condition must be associated with chronic renal failure.

CALCIUM Tablet (chewable) 500 mg (as carbonate), 120

11726E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*27.35	28.60	^a Cal-500 [PP]

CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

3116B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	1	..	*27.35	28.60	^a Cal-500 [PP]

POTASSIUM*Potassium***■ POTASSIUM CHLORIDE**

Note For item codes 2642C and 1841X, pharmaceutical benefits that have the form tablet 600 mg (sustained release) are equivalent for the purposes of substitution.

potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200

1841X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	19.65	20.90	Span-K [AS]

■ POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE**potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet, 60**

3012M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	21.16	22.41	Chlorvescent [AS]

OTHER MINERAL SUPPLEMENTS*Magnesium***■ MAGNESIUM ASPARTATE DIHYDRATE****Authority required (STREAMLINED)****5506**

Hypomagnesaemia

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

Authority required (STREAMLINED)**5466**

Chronic renal disease

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

magnesium aspartate dihydrate 500 mg (magnesium 37.4 mg) tablet, 50

5146W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.50	18.75	MagMin (PBS) [BB]	Mag-Sup [PP]

■ OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS**OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS***Amino acids and derivatives***■ BETAINE****Authority required**

Homocystinuria

Clinical criteria:

- The treatment must be as adjunctive therapy to current standard care, **AND**
- The condition must be treated by or in consultation with a metabolic physician.

The name of the specialist must be included in the authority application.

betaine 1 g/g powder for oral liquid, 180 g

10119N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	566.26	40.30	Cystadane [RJ]

*Various alimentary tract and metabolism products***■ SAPROPTERIN**

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Hyperphenylalaninaemia

Treatment Phase: Continuing

Clinical criteria:

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously been issued with an authority prescription for this drug; OR
- Patient must have accessed non-PBS-subsidised treatment prior to 1 May 2014.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.

sapropterin dihydrochloride 100 mg soluble tablet, 30

10087X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*5312.17	40.30	Kuvan [IO]

■ SAPROPTERIN

Note Special Pricing Arrangements apply.

Authority required

Hyperphenylalaninemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Grandfather treatment

Treatment criteria:

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 May 2019, **AND**
- Patient must have demonstrated a response to treatment with this drug of greater than or equal to a 30% reduction in phenylalanine levels from baseline during initial responsiveness testing, **AND**
- Patient must have a documented diagnosis of PKU.

Population criteria:

- Patient must have been under 18 years of age at the time treatment with this drug was initiated for this condition. Blood phenylalanine levels must be based on measurements taken during stable periods of the condition.

Dietary phenylalanine intake must be maintained at a constant level.

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

sapropterin dihydrochloride 100 mg soluble tablet, 30

11686C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	..	..	*5312.17	40.30	Kuvan [IO]

NP

■ SAPROPTERIN

Note Special Pricing Arrangements apply.

Note Patient will be eligible for a maximum of one PBS-subsidised prescription as initial therapy to enable their response to treatment with sapropterin to be assessed.

Authority required

Hyperphenylalaninemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Initial treatment - responsiveness testing

Treatment criteria:

- Must be treated by a metabolic physician.

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a baseline blood phenylalanine level above 360 micromole per L and be less than one month of age; OR
- Patient must have a baseline blood phenylalanine level above 600 micromole per L and be more than one month of age, **AND**
- The treatment must be for the purpose of initial responsiveness testing for a period of 24 hours in a patient less than one month of age; OR
- The treatment must be for the purpose of initial responsiveness testing for a period of 7 days in a patient aged more than one month.

Population criteria:

- Patient must be under 18 years of age.

Dietary phenylalanine intake must be maintained at a constant level.

Patients or their parent/guardian should be assessed for their ability to comply with the sapropterin protocol and PKU diet prior to conducting initial responsiveness testing.

sapropterin dihydrochloride 100 mg soluble tablet, 30

11676M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*2697.16	40.30	Kuvan [IO]

■ SAPROPTERIN

Note Patients will be eligible for a maximum of one script as initial therapy to enable their response to treatment with sapropterin to be assessed.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Hyperphenylalaninaemia

Treatment Phase: Initial

Clinical criteria:

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency. Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.

sapropterin dihydrochloride 100 mg soluble tablet, 30

10086W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	..	..	*5312.17	40.30	Kuvan [IO]

■ SAPROPTERIN

Note Special Pricing Arrangements apply.

Authority required

Hyperphenylalaninemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment under the Initial treatment - responsiveness testing restriction with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug of greater than or equal to a 30% reduction in phenylalanine levels from baseline during initial responsiveness testing.

Population criteria:

- Patient must have been under 18 years of age at the time treatment with this drug was initiated for this condition. Blood phenylalanine levels must be based on measurements taken during stable periods of the condition. Dietary phenylalanine intake must be maintained at a constant level.

Authority required

Hyperphenylalaninemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Subsequent continuing

Treatment criteria:

- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the Grandfather treatment restriction, **AND**
- Patient must be undergoing regular phenylalanine testing and assessment of adherence to dietary modifications.

Population criteria:

- Patient must have been under 18 years of age at the time treatment with this drug was initiated for this condition.

sapropterin dihydrochloride 100 mg soluble tablet, 30

11691H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*5312.17	40.30	Kuvan [IO]

NP

■ BLOOD AND BLOOD FORMING ORGANS**■ ANTITHROMBOTIC AGENTS****ANTITHROMBOTIC AGENTS**

Vitamin K antagonists

■ WARFARIN

Caution The listed brands have NOT been shown to be bioequivalent and should not be interchanged.

warfarin sodium 3 mg tablet, 50

2844Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	16.42	17.67	Marevan [FM]

NP

warfarin sodium 2 mg tablet, 50

2209G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	16.35	17.60	Coumadin [QA]

warfarin sodium 1 mg tablet, 50

2843P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	16.16	17.41	Coumadin [QA]	Marevan [FM]

warfarin sodium 5 mg tablet, 50

2211J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	16.86	18.11	Coumadin [QA]	Marevan [FM]

*Heparin group***■ DALTEPARIN SODIUM****dalteparin sodium 2500 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes**

8603T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*84.09	40.30	Fragmin [PF]

dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes

8271H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	57.23	40.30	Fragmin [PF]

dalteparin sodium 5000 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes

2816F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*87.11	40.30	Fragmin [PF]

dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes

5445N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	99.56	40.30	Fragmin [PF]

dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes

8269F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	73.93	40.30	Fragmin [PF]

■ DALTEPARIN SODIUMRestricted benefit

Haemodialysis

dalteparin sodium 2500 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes

8641T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*84.09	40.30	Fragmin [PF]

dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes

8643X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*102.99	40.30	Fragmin [PF]

dalteparin sodium 5000 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes

8642W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*87.11	40.30	Fragmin [PF]

dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes

1296F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*187.65	40.30	Fragmin [PF]

dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes

1229Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*136.39	40.30	Fragmin [PF]

■ DALTEPARIN SODIUM**Note** No applications for increased maximum quantities will be authorised.Restricted benefit

Symptomatic venous thromboembolism

Treatment Phase: Management

Clinical criteria:

- Patient must have a solid tumour(s).

dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8956J	3	5	..	*148.72	40.30	Fragmin [PF]

dalteparin sodium 18 000 anti-Xa units/0.72 mL injection, 10 x 0.72 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8960N	3	5	..	*398.98	40.30	Fragmin [PF]

dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8958L	3	5	..	*278.68	40.30	Fragmin [PF]

dalteparin sodium 15 000 anti-Xa units/0.6 mL injection, 10 x 0.6 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8959M	3	5	..	*333.31	40.30	Fragmin [PF]

dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8957K	3	5	..	*199.09	40.30	Fragmin [PF]

▪ ENOXAPARIN SODIUM**enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8262W	1	1	..	64.63	40.30	^a Clexane [SW]	^a Enoxaparin Winthrop [WA]

enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8264Y	1	1	..	85.96	40.30	^a Clexane [SW]	^a Enoxaparin Winthrop [WA]

enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8558K	2	1	..	*82.79	40.30	^a Clexane [SW]	^a Enoxaparin Winthrop [WA]

enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8510X	2	1	..	*85.81	40.30	^a Clexane [SW]	^a Enoxaparin Winthrop [WA]

enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8263X	1	1	..	72.63	40.30	^a Clexane [SW]	^a Enoxaparin Winthrop [WA]

▪ ENOXAPARIN SODIUM**Restricted benefit**

Haemodialysis

enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8640R	2	3	..	*117.79	40.30	^a Clexane [SW]	^a Enoxaparin Winthrop [WA]

enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5435C	2	3	..	*160.45	40.30	^a Clexane [SW]	^a Enoxaparin Winthrop [WA]

enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8716R	2	3	..	*82.79	40.30	^a Clexane [SW]	^a Enoxaparin Winthrop [WA]

enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8639Q	2	3	..	*85.81	40.30	^a Clexane [SW]	^a Enoxaparin Winthrop [WA]

enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5434B	2	3	..	*133.79	40.30	^a Clexane [SW]	^a Enoxaparin Winthrop [WA]

■ HEPARIN SODIUM

heparin sodium 5000 units/0.2 mL injection, 5 x 0.2 mL ampoules

1466E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.80	25.05	Hospira Pty Limited [PF]

heparin sodium 35 000 units/35 mL injection, 35 mL vial

1076P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*304.27	40.30	Hospira Pty Limited [PF]

heparin sodium 5000 units/5 mL injection, 50 x 5 mL ampoules

1463B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	72.70	40.30	Pfizer Australia Pty Ltd [PF]

■ NADROPARIN

nadroparin calcium 19 000 anti-Xa units/mL injection, 2 x 1 mL syringes

10707M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*190.24	40.30	Fraxiparine Forte [AS]

nadroparin calcium 2850 anti-Xa units/0.3 mL injection, 2 x 0.3 mL syringes

10686K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	..	..	*65.19	40.30	Fraxiparine [AS]

nadroparin calcium 15 200 anti-Xa units/0.8 mL injection, 2 x 0.8 mL syringes

10725L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*154.49	40.30	Fraxiparine Forte [AS]

nadroparin calcium 11 400 anti-Xa units/0.6 mL injection, 2 x 0.6 mL syringes

10706L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*118.74	40.30	Fraxiparine Forte [AS]

nadroparin calcium 9500 anti-Xa units/mL injection, 2 x 1 mL syringes

10702G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*100.89	40.30	Fraxiparine [AS]

nadroparin calcium 1900 anti-Xa units/0.2 mL injection, 2 x 0.2 mL syringes

10735B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	..	..	*47.29	40.30	Fraxiparine [AS]

nadroparin calcium 3800 anti-Xa units/0.4 mL injection, 2 x 0.4 mL syringes

10685J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	..	..	*82.99	40.30	Fraxiparine [AS]

nadroparin calcium 7600 anti-Xa units/0.8 mL injection, 2 x 0.8 mL syringes

10734Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*82.99	40.30	Fraxiparine [AS]

nadroparin calcium 5700 anti-Xa units/0.6 mL injection, 2 x 0.6 mL syringes

10716B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	..	..	*118.79	40.30	Fraxiparine [AS]

■ NADROPARIN

Restricted benefit

Haemodialysis

nadroparin calcium 2850 anti-Xa units/0.3 mL injection, 2 x 0.3 mL syringes

10701F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	3	..	*65.19	40.30	Fraxiparine [AS]

nadroparin calcium 9500 anti-Xa units/mL injection, 2 x 1 mL syringes

10733X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	3	..	*190.29	40.30	Fraxiparine [AS]

nadroparin calcium 1900 anti-Xa units/0.2 mL injection, 2 x 0.2 mL syringes

10687L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	3	..	*47.29	40.30	Fraxiparine [AS]

nadroparin calcium 3800 anti-Xa units/0.4 mL injection, 2 x 0.4 mL syringes

10717C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	3	..	*82.99	40.30	Fraxiparine [AS]

nadroparin calcium 7600 anti-Xa units/0.8 mL injection, 2 x 0.8 mL syringes

10740G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	3	..	*154.49	40.30	Fraxiparine [AS]

nadroparin calcium 5700 anti-Xa units/0.6 mL injection, 2 x 0.6 mL syringes

10718D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	3	..	*118.79	40.30	Fraxiparine [AS]

Platelet aggregation inhibitors excl. heparin**■ ASPIRIN****Restricted benefit**

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

aspirin 300 mg effervescent tablet, 96

1010E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	13.00	14.25	Solprin [RC]

■ ASPIRIN**Restricted benefit**

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

aspirin 100 mg tablet, 112

8202Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	13.32	14.57	Spren 100 [OW]

■ CLOPIDOGREL

Note Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

Note Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

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.

Authority required (STREAMLINED)**4166**

Acute coronary syndrome (myocardial infarction or unstable angina)

Clinical criteria:

- The treatment must be in combination with aspirin.

Authority required (STREAMLINED)**4165**

Cardiac stent insertion

Clinical criteria:

- The treatment must be in combination with aspirin, **AND**
- The treatment must follow insertion of a cardiac stent.

clopidogrel 75 mg tablet, 28

2275R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.57	16.82	^a Clopidogrel-GA [EA] ^a Clovix 75 [RW]	^a Clopidogrel GH [GQ] ^a Plidogrel [RF]

clopidogrel 75 mg tablet, 28

9317J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.57	16.82	^a APO-Clopidogrel [TX] ^a Chem mart Clopidogrel [CH] ^a Clopidogrel Sandoz [SZ] ^a Iscover [AV] ^a Plavix [SW]	^a Blooms the Chemist Clopidogrel [IB] ^a Clopidogrel AN [EA] ^a Clopidogrel Winthrop [WA] ^a Piax [AF] ^a Terry White Chemists Clopidogrel [TW]

■ CLOPIDOGREL

Note Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

Note Not for prophylaxis of deep vein thrombosis or peripheral arterial 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.

Authority required (STREAMLINED)**5517**

Prevention of recurrence of myocardial infarction or unstable angina

Clinical criteria:

- Patient must have a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

Authority required (STREAMLINED)**5524**

Prevention of recurrence of myocardial infarction or unstable angina

Clinical criteria:

- Patient must be in one whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

Authority required (STREAMLINED)**5525**

Prevention of recurrence of myocardial infarction or unstable angina

Clinical criteria:

- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

Authority required (STREAMLINED)**5459**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

Clinical criteria:

- Patient must have a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin.

Authority required (STREAMLINED)**5436**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

Clinical criteria:

- Patient must be in one whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

Authority required (STREAMLINED)**5508**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

Clinical criteria:

- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

clopidogrel 75 mg tablet, 28

8358X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.57	16.82	^a APO-Clopidogrel [TX] ^a Chem mart Clopidogrel [CH] ^a Clopidogrel Sandoz [SZ] ^a Iscover [AV] ^a Plavacor 75 [CR] ^a Terry White Chemists Clopidogrel [TW]	^a Blooms the Chemist Clopidogrel [IB] ^a Clopidogrel AN [EA] ^a Clopidogrel Winthrop [WA] ^a Piax [AF] ^a Plavix [SW]

clopidogrel 75 mg tablet, 28

9354H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.57	16.82	^a Clopidogrel-GA [EA] ^a Clovix 75 [RW]	^a Clopidogrel GH [GQ] ^a Plidogrel [RF]

■ CLOPIDOGREL + ASPIRIN

Note Not for prophylaxis of deep vein thrombosis or peripheral arterial 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.

Authority required (STREAMLINED)**5488**

Acute coronary syndrome (myocardial infarction or unstable angina)

Authority required (STREAMLINED)**5443**

Cardiac stent insertion

Clinical criteria:

- The treatment must follow insertion of a cardiac stent.

Authority required (STREAMLINED)**5517**

Prevention of recurrence of myocardial infarction or unstable angina

Clinical criteria:

- Patient must have a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

clopidogrel 75 mg + aspirin 100 mg tablet, 30

9296G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.86	17.11	^a APO-Clopidogrel/Aspirin 75/100 [TX]	^a Clopidogrel/Aspirin Actavis 75/100 [EA]
						^a CLOPIDOGREL/ASPIRIN AN 75/100 [ED]	^a Clopidogrel/Aspirin Sandoz 75/100 [SZ]
						^a Clopidogrel Winthrop plus aspirin [WA]	^a CoPlavix [SW]
						^a DuoCover [AV]	^a DuoPlidogrel [GZ]
						^a Piax Plus Aspirin [AF]	

▪ **DIPYRIDAMOLE**

Note Shared Care Model:

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

Restricted benefit

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

Clinical criteria:

- The treatment must be as adjunctive therapy with low-dose aspirin.

Restricted benefit

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

Clinical criteria:

- Patient must be one in whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

Restricted benefit

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

Clinical criteria:

- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

dipyridamole 200 mg modified release capsule, 60

8335Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	33.06	34.31	Persantin SR [BY]

▪ **DIPYRIDAMOLE + ASPIRIN**

Note Shared Care Model:

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

Restricted benefit

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

dipyridamole 200 mg + aspirin 25 mg modified release capsule, 60

8382E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.96	35.21	^a Asasantin SR [BY]	^a Diasp SR [RW]

▪ **EPTIFIBATIDE**

Authority required (STREAMLINED)

6435

Coronary artery disease

Treatment criteria:

- Patient must be undergoing non-urgent percutaneous intervention with intracoronary stenting.

eptifibatide 20 mg/10 mL injection, 10 mL vial

8683B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*205.35	40.30	Integrilin [MK]

eptifibatide 75 mg/100 mL injection, 100 mL vial

8684C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*824.80	40.30	Integrilin [MK]

▪ **PRASUGREL**

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.

Authority required (STREAMLINED)**6454**

Acute coronary syndrome (myocardial infarction or unstable angina)

Clinical criteria:

- The treatment must be managed by percutaneous coronary intervention in combination with aspirin.

prasugrel 10 mg tablet, 28

9496T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	97.85	40.30	Effient [LY]

prasugrel 5 mg tablet, 28

9495R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	89.22	40.30	Effient [LY]

■ TICAGRELOR**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.

Authority required (STREAMLINED)**5746**

Acute coronary syndrome (myocardial infarction or unstable angina)

Clinical criteria:

- The treatment must be in combination with aspirin.

ticagrelor 90 mg tablet, 56

1418P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	134.61	40.30	Brilinta [AP]

■ TIROFIBAN**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.

Authority required (STREAMLINED)**5782**

High risk of unstable angina

Clinical criteria:

- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have pain lasting longer than 20 minutes.

Authority required (STREAMLINED)**5809**

High risk of unstable angina

Clinical criteria:

- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours.

Authority required (STREAMLINED)**5691**

Non-Q-wave myocardial infarction

tirofiban 12.5 mg/50 mL injection, 50 mL vial

8350L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	208.27	40.30	^a Aggrastat [AS]	^a Tirofiban AC [JO]
						^a Tirofiban Juno [JU]	

Enzymes**■ RETEPLASE****Note Shared Care Model:**

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

Restricted benefit

Acute myocardial infarction

Clinical criteria:

- The treatment must be administered within 6 hours of the onset of attack.

reteplase 10 units (17.4 mg) injection [2 x 10 unit vials] (&) inert substance diluent [2 x 10 mL syringes], 1 pack

8253J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	1692.18	40.30	Rapilysin 10 U [TB]

■ TENECTEPLASE**Note Shared Care Model:**

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

Restricted benefit

Acute myocardial infarction

Clinical criteria:

- The treatment must be administered within 12 hours of onset of attack.

tenecteplase 40 mg injection [1 vial] (&) inert substance diluent [8 mL syringe], 1 pack

8526R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	1861.58	40.30	Metalyse [BY]

tenecteplase 50 mg injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack

8527T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	1956.27	40.30	Metalyse [BY]

Direct thrombin inhibitors**■ BIVALIRUDIN****Authority required (STREAMLINED)**

4919

Coronary artery disease

Treatment criteria:

- Patient must be undergoing percutaneous coronary intervention.

bivalirudin 250 mg injection, 1 vial

8844L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	533.57	40.30	^a Angiomax [XM]	^a Bivalirudin APOTEX [TX]

■ DABIGATRAN

Note No 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 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.

Authority required (STREAMLINED)

4402

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total hip replacement.

Clinical criteria:

- Patient must require up to 30 days supply to complete a course of treatment.

dabigatran etexilate 110 mg capsule, 60

9321N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	88.77	40.30	Pradaxa [BY]

dabigatran etexilate 75 mg capsule, 60

9320M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	110.18	40.30	Pradaxa [BY]

■ DABIGATRAN

Note No 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 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.

Authority required (STREAMLINED)

4369

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total hip replacement.

Clinical criteria:

- Patient must require up to 20 days supply to complete a course of treatment.

dabigatran etexilate 110 mg capsule, 10

9319L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*37.25	38.50	Pradaxa [BY]

dabigatran etexilate 75 mg capsule, 10

9318K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*44.39	40.30	Pradaxa [BY]

■ DABIGATRAN

Note No 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 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.

Authority required (STREAMLINED)**4381**

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total knee replacement.

Clinical criteria:

- Patient must require up to 10 days of therapy.

dabigatran etexilate 110 mg capsule, 10

9323Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*37.25	38.50	Pradaxa [BY]

dabigatran etexilate 75 mg capsule, 10

9322P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*44.39	40.30	Pradaxa [BY]

■ DABIGATRAN**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.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**4269**

Prevention of stroke or systemic embolism

Clinical criteria:

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- age 75 years or older;
- hypertension;
- diabetes mellitus;
- heart failure and/or left ventricular ejection fraction 35% or less.

dabigatran etexilate 110 mg capsule, 60

2753X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.77	40.30	Pradaxa [BY]

dabigatran etexilate 150 mg capsule, 60

2769R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.77	40.30	Pradaxa [BY]

Direct factor Xa inhibitors

■ APIXABAN

Note No 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 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.

Authority required (STREAMLINED)

4402

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total hip replacement.

Clinical criteria:

- Patient must require up to 30 days supply to complete a course of treatment.

apixaban 2.5 mg tablet, 60

5061J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	93.31	40.30	Eliquis [BQ]

■ APIXABAN

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.

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

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

Authority required (STREAMLINED)

4098

Deep vein thrombosis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)

5098

Pulmonary embolism

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic pulmonary embolism.

apixaban 5 mg tablet, 28

10414D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	49.67	40.30	Eliquis [BQ]

■ APIXABAN

Note No 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 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.

Authority required (STREAMLINED)

4382

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total knee replacement.

Clinical criteria:

- Patient must require up to 15 days of therapy.

Authority required (STREAMLINED)

4409

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total hip replacement.

Clinical criteria:

- Patient must require up to 15 days supply to complete a course of treatment.

apixaban 2.5 mg tablet, 30

5054B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	52.40	40.30	Eliquis [BQ]

■ APIXABAN

Note No 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 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.

Authority required (STREAMLINED)**4381**

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total knee replacement.

Clinical criteria:

- Patient must require up to 10 days of therapy.

Authority required (STREAMLINED)**4359**

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total hip replacement.

Clinical criteria:

- Patient must require up to 10 days supply to complete a course of treatment.

apixaban 2.5 mg tablet, 20

5500L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	38.76	40.01	Eliquis [BQ]

■ APIXABAN

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.

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

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

Authority required (STREAMLINED)**4269**

Prevention of stroke or systemic embolism

Clinical criteria:

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- age 75 years or older;
- hypertension;
- diabetes mellitus;
- heart failure and/or left ventricular ejection fraction 35% or less.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**4132**

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a history of venous thromboembolism.

apixaban 2.5 mg tablet, 60

2744K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	93.31	40.30	Eliquis [BQ]

■ APIXABAN

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.

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

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

Authority required (STREAMLINED)

4269

Prevention of stroke or systemic embolism

Clinical criteria:

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- (ii) age 75 years or older;
- (iii) hypertension;
- (iv) diabetes mellitus;
- (v) heart failure and/or left ventricular ejection fraction 35% or less.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4099

Deep vein thrombosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)

5083

Pulmonary embolism

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic pulmonary embolism.

apixaban 5 mg tablet, 60

2735Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	93.31	40.30	Eliquis [BQ]

▪ **RIVAROXABAN**

Note No 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 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.

Authority required (STREAMLINED)

4369

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total hip replacement.

Clinical criteria:

- Patient must require up to 20 days supply to complete a course of treatment.

rivaroxaban 10 mg tablet, 10

9465E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	38.65	39.90	Xarelto [BN]

▪ **RIVAROXABAN**

Note No 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 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.

Authority required (STREAMLINED)

4402

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total hip replacement.

Clinical criteria:

- Patient must require up to 30 days supply to complete a course of treatment.

rivaroxaban 10 mg tablet, 30

9467G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	92.99	40.30	Xarelto [BN]

rivaroxaban 10 mg tablet, 15

9466F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	52.24	40.30	Xarelto [BN]

■ RIVAROXABAN

Note No 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 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.

Authority required (STREAMLINED)**4381**

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total knee replacement.

Clinical criteria:

- Patient must require up to 10 days of therapy.

rivaroxaban 10 mg tablet, 10

9468H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	38.65	39.90	Xarelto [BN]

■ RIVAROXABAN

Note No 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 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.

Authority required (STREAMLINED)**4382**

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total knee replacement.

Clinical criteria:

- Patient must require up to 15 days of therapy.

rivaroxaban 10 mg tablet, 15

9469J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	52.24	40.30	Xarelto [BN]

■ RIVAROXABAN**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.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**4132**

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a history of venous thromboembolism.

rivaroxaban 10 mg tablet, 30

11633G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	92.99	40.30	Xarelto [BN]

■ RIVAROXABAN**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.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4269

Prevention of stroke or systemic embolism

Clinical criteria:

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

rivaroxaban 15 mg tablet, 28

2691P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	87.56	40.30	Xarelto [BN]

■ **RIVAROXABAN**

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.

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

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

Authority required (STREAMLINED)

4098

Deep vein thrombosis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)

4260

Pulmonary embolism

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic pulmonary embolism.

Note Special Pricing Arrangements apply.

rivaroxaban 15 mg tablet, 42

2160Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	125.60	40.30	Xarelto [BN]

■ **RIVAROXABAN**

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.

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

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

Authority required (STREAMLINED)

4099

Deep vein thrombosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)

4132

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a history of venous thromboembolism.

Authority required (STREAMLINED)**4268**

Pulmonary embolism

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have confirmed acute symptomatic pulmonary embolism.

Note Special Pricing Arrangements apply.**Authority required (STREAMLINED)****4269**

Prevention of stroke or systemic embolism

Clinical criteria:

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- (ii) age 75 years or older;
- (iii) hypertension;
- (iv) diabetes mellitus;
- (v) heart failure and/or left ventricular ejection fraction 35% or less.

Note Special Pricing Arrangements apply.**rivaroxaban 20 mg tablet, 28**

2268J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	87.56	40.30	Xarelto [BN]

NP

Other antithrombotic agents**▪ FONDAPARINUX****Note** No 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 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.

Authority required (STREAMLINED)**5781**

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing major hip surgery.

Authority required (STREAMLINED)**5808**

Prevention of venous thromboembolism

Treatment criteria:

- Patient must be undergoing total knee replacement.

fondaparinux sodium 2.5 mg/0.5 mL injection, 2 x 0.5 mL syringes

8775W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3.5	..	..	*115.85	40.30	Arixtra [AS]

NP

▪ ANTIHEMORRHAGICS**ANTIFIBRINOLYTICS****Amino acids****▪ TRANEXAMIC ACID****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.

tranexamic acid 500 mg tablet, 100

2180R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	40.66	40.30	^a APO-Tranexamic Acid [TX]	^a Cyklokapron [PF]

NP

■ ANTIANEMIC PREPARATIONS

IRON PREPARATIONS

Iron bivalent, oral preparations

■ FERROUS FUMARATE

Restricted benefit

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

ferrous fumarate 200 mg (iron 65.7 mg) tablet, 60

8985X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	18.15	19.40	Ferro-tab [AE]

■ FERROUS SULFATE

ferrous sulfate heptahydrate 30 mg/mL (iron 6 mg/mL) oral liquid, 250 mL

8815Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	21.09	22.34	Ferro-Liquid [AE]

Iron, parenteral preparations

■ FERRIC CARBOXYMALTOSE

Note Special Pricing Arrangements apply.

iron (as ferric carboxymaltose) 1 g/20 mL injection, 20 mL vial

11702X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	307.87	40.30	Ferinject [VL]

iron (as ferric carboxymaltose) 500 mg/10 mL injection, 10 mL vial

10104T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*307.87	40.30	Ferinject [VL]

■ FERRIC DERISOMALTOSE

Note Special Pricing Arrangements apply.

iron (as ferric derisomaltose) 500 mg/5 mL injection, 5 mL vial

11615H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*307.87	40.30	Monofer [PF]

■ IRON POLYMALTOSE

iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

2593L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	24.08	25.33	Ferrosig [SI]

■ IRON POLYMALTOSE

Authority required (STREAMLINED)

4302

Iron deficiency anaemia

Treatment criteria:

- Patient must be undergoing chronic haemodialysis.

iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

2805P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.08	25.33	Ferrosig [SI]

■ IRON SUCROSE

iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules

10229J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	37.55	38.80	Venofer [VL]

■ IRON SUCROSE

Authority required (STREAMLINED)

4302

Iron deficiency anaemia

Treatment criteria:

- Patient must be undergoing chronic haemodialysis.

iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules

8807M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	37.55	38.80	Venofer [VL]

*Iron in combination with folic acid***■ FERROUS FUMARATE + FOLIC ACID****Restricted benefit**

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

ferrous fumarate 310 mg (iron 100 mg) + folic acid 350 microgram tablet, 60

9011G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	19.17	20.42	Ferro-f-tab [AE]

VITAMIN B12 AND FOLIC ACID*Vitamin B12 (cyanocobalamin and analogues)***■ HYDROXOCOBALAMIN****Note** One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B₁₂ deficiencies.**Note** Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.**Restricted benefit**

Pernicious anaemia

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Proven vitamin B12 deficiencies other than pernicious anaemia

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Anaemias associated with vitamin B12 deficiency

Clinical criteria:

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

2162T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.75	17.00	^a Cobal-B12 [JU]	^a Vita-B12 [GH]

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

9048F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.75	17.00	^a Hydroxo-B12 [AS]	^a Neo-B12 [PF]

*Folic acid and derivatives***■ FOLIC ACID****Restricted benefit**

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

folic acid 500 microgram tablet, 100

2958Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*15.55	16.80	^a Foltabs 500 [PP]	^a Megafof 0.5 [AF]

■ FOLIC ACID**Note** The 5 mg strength tablet should be used in malabsorption states only.**Restricted benefit**

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

folic acid 5 mg tablet, 100

1437P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*17.77	19.02	Megafof 5 [AF]

BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

BLOOD AND RELATED PRODUCTS

Blood substitutes and plasma protein fractions

HYDROXYETHYL STARCH 130/0.4 + SODIUM CHLORIDE

HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1

9487H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	..	..	*44.56	40.30	Voluven 6% [PK]

OTHER HEMATOLOGICAL AGENTS

OTHER HEMATOLOGICAL AGENTS

Drugs used in hereditary angioedema

ICATIBANT

Note Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)

Authority required

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Initial

Clinical criteria:

- Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency, **AND**
- Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema, **AND**
- The condition must be assessed by a clinical immunologist; OR
- The condition must be assessed by a respiratory physician; OR
- The condition must be assessed by a specialist allergist; OR
- The condition must be assessed by a general physician experienced in the management of patients with hereditary angioedema.

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

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

Increased maximum quantities will be limited to 12 injections per authority prescription.

Authority required

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Continuing

Clinical criteria:

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

Increased maximum quantities will be limited to 12 injections per authority prescription.

icatibant 30 mg/3 mL injection, 3 mL syringe

1976B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	2455.87	40.30	Firazyr [ZI]

CARDIOVASCULAR SYSTEM

CARDIAC THERAPY

CARDIAC GLYCOSIDES

Digitalis glycosides

DIGOXIN

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.

digoxin 250 microgram tablet, 100

1322N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	15.21	16.46	^a Sigmaxin [FM]
			^b 2.56	17.77	16.46	^a Lanoxin [QA]

digoxin 50 microgram/mL oral liquid, 60 mL

3164M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*41.69	40.30	Lanoxin [QA]

digoxin 62.5 microgram tablet, 200

2605D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	1	..	14.96	16.21	^a Sigmaxin-PG [FM]	
			^B 2.56	17.52	16.21	^a Lanoxin-PG [QA]	

ANTIARRHYTHMICS, CLASS I AND III

Antiarrhythmics, class Ia

DISOPYRAMIDE

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.

disopyramide 100 mg capsule, 100

2923W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	27.52	28.77	Rythmodan [SW]	

Antiarrhythmics, class Ib

LIDOCAINE (LIGNOCAINE)

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.

lidocaine (lignocaine) hydrochloride 10% (500 mg/5 mL) injection, 10 x 5 mL ampoules

2876J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	..	..	27.84	29.09	Xylocard 500 [AS]	

Antiarrhythmics, class Ic

FLECAINIDE

Caution Flecainide acetate should be avoided in patients with poor cardiac function.

Note Shared Care Model:

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

Restricted benefit

Serious supra-ventricular cardiac arrhythmias

Restricted benefit

Serious ventricular cardiac arrhythmias

Clinical criteria:

- The treatment must be initiated in a hospital.

flecainide acetate 50 mg tablet, 60

1088G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	34.36	35.61	^a APO-Flecainide [TX]	^a Flecainide Sandoz [SZ]
						^a Tambacor [IL]	

flecainide acetate 100 mg tablet, 60

1090J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	39.84	40.30	^a APO-Flecainide [TX]	^a Flecainide Sandoz [SZ]
						^a Flecatag [AF]	^a Tambacor [IL]

Antiarrhythmics, class III

AMIODARONE

Note This drug has been reported to cause frequent and potentially serious toxicity.

Note Regular monitoring of hepatic and thyroid function is recommended.

Note Shared Care Model:

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

Restricted benefit

Severe cardiac arrhythmias

amiodarone hydrochloride 200 mg tablet, 30

2343H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	19.22	20.47	^a Amiodarone Sandoz [SZ]	^a APO-Amiodarone [TX]
						^a Aratac 200 [AF]	^a Cordarone X 200 [SW]
						^a GenRx Amiodarone [GX]	^a Rithmik 200 [RW]

amiodarone hydrochloride 100 mg tablet, 30

2344J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.83	17.08	^a Aratac 100 [AF]	^a Cordarone X 100 [SW]

■ SOTALOL**Note Shared Care Model:**

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

Restricted benefit

Severe cardiac arrhythmias

sotalol hydrochloride 80 mg tablet, 60

8398B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.69	15.94	^a APO-Sotalol [TX]	^a Cardol [AF]
						^a Solavert [RF]	^a Sotalol Sandoz [SZ]
			^B 4.33	19.02	15.94	^a Sotacor [RW]	

sotalol hydrochloride 160 mg tablet, 60

2043M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.39	19.64	^a APO-Sotalol [TX]	^a Cardol [AF]
						^a Solavert [RF]	^a Sotalol Sandoz [SZ]
			^B 4.33	22.72	19.64	^a Sotacor [RW]	

CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES*Adrenergic and dopaminergic agents***■ ADRENALINE (EPINEPHRINE)****adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

1016L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	21.14	22.39	Link Medical Products Pty Ltd [LM]

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

5004J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	21.14	22.39	Link Medical Products Pty Ltd [LM]

■ ADRENALINE (EPINEPHRINE)

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

Note Authority approvals will be limited to a maximum quantity of 2 auto-injectors at any one time.

Note No applications for repeats will be authorised.

Authority required

Acute allergic reaction with anaphylaxis

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

Clinical criteria:

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
 - Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
 - Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
 - Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.
- The name of the specialist consulted must be provided at the time of application for initial supply.

Authority required

Acute allergic reaction with anaphylaxis

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

Clinical criteria:

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

Authority required

Acute allergic reaction with anaphylaxis

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

Clinical criteria:

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

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

8697R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	83.72	40.30	^a Adrenaline Jr Mylan [AF]	^a EpiPen Jr. [AL]

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

8698T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	83.72	40.30	^a Adrenaline Mylan [AF]	^a EpiPen [AL]

VASODILATORS USED IN CARDIAC DISEASES*Organic nitrates***■ GLYCERYL TRINITRATE****glyceryl trinitrate 15 mg/24 hours patch, 30**

8119H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	32.75	34.00	Minitran 15 [IL]

glyceryl trinitrate 10 mg/24 hours patch, 30

1516T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	32.75	34.00	Transiderm-Nitro 50 [SZ]

glyceryl trinitrate 10 mg/24 hours patch, 30

8028M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	32.75	34.00	Minitran 10 [IL]

glyceryl trinitrate 600 microgram sublingual tablet, 100

1459T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	18.79	20.04	Nitrostat [PF] ^a Lycinate [RF] ^b 2.56 21.35 20.04 ^a Anginine Stabilised [RW]

glyceryl trinitrate 600 microgram sublingual tablet, 100

5108W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	18.79	20.04	Nitrostat [PF] ^a Lycinate [RF] ^b 2.56 21.35 20.04 ^a Anginine Stabilised [RW]

glyceryl trinitrate 5 mg/24 hours patch, 30

1515R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	27.70	28.95	Transiderm-Nitro 25 [SZ]

glyceryl trinitrate 5 mg/24 hours patch, 30

8027L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	27.70	28.95	Minitran 5 [IL]

glyceryl trinitrate 300 microgram sublingual tablet, 100

11027J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	18.79	20.04	Nitrostat [PF]

glyceryl trinitrate 300 microgram sublingual tablet, 100

11051P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	18.79	20.04	Nitrostat [PF]

■ GLYCERYL TRINITRATE**Note** The spray should not be inhaled.**glyceryl trinitrate 400 microgram/actuation spray, 200 actuations**

8171C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	23.40	24.65	Nitrolingual Pumpspray [SW]

■ ISOSORBIDE DINITRATE**isosorbide dinitrate 5 mg sublingual tablet, 100**

2588F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*18.57	19.82	Isordil Sublingual [RW]

■ ISOSORBIDE MONONITRATE

isosorbide mononitrate 120 mg modified release tablet, 30

8273K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.80	20.05	^a Monodur 120 mg [IY]
			^B 3.37	22.17	20.05	^a Imdur 120 mg [IX]

isosorbide mononitrate 60 mg modified release tablet, 30

1558B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.16	16.41	^a APO-Isosorbide Mononitrate [TX]	^a Chem mart Isosorbide Mononitrate [CH]
						^a Duride [AF]	^a GenRx Isosorbide Mononitrate [GX]
						^a ISOBIDE MR [RF]	^a Isomonit [SZ]
						^a Isosorbide AN [EA]	^a Terry White Chemists Isosorbide Mononitrate [TW]
						^B 2.48	^a Monodur 60 mg [IY]
			^B 3.37	18.53	16.41	^a Imdur Durule [IX]	

Other vasodilators used in cardiac diseases

■ NICORANDIL

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.

nicorandil 10 mg tablet, 60

8228C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	21.71	22.96	^a Ikorel [SW]	^a Ikotab [QA]

nicorandil 20 mg tablet, 60

8229D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	25.73	26.98	^a Ikorel [SW]	^a Ikotab [QA]

■ PERHEXILINE

Note Regular monitoring of drug serum levels is recommended.

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.

Authority required (STREAMLINED)

5592

Angina

Clinical criteria:

- The condition must not be responding to other therapy.

perhexiline maleate 100 mg tablet, 100

1822X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	52.97	40.30	Pexsig [QA]

OTHER CARDIAC PREPARATIONS

Other cardiac preparations

■ IVABRADINE

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.

Authority required (STREAMLINED)

4979

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II or III, **AND**
- Patient must be in sinus rhythm, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%, **AND**
- Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.

Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest.

The ECG or echocardiography, result must be documented in the patient's medical records when treatment is initiated.

ivabradine 7.5 mg tablet, 56

2960T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.84	40.30	^a APO-Ivabradine [TX]	^a Coralan [SE]

ivabradine 5 mg tablet, 56

10012Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.84	40.30	^a APO-Ivabradine [TX]	^a Coralan [SE]

■ ANTIHYPERTENSIVES

ANTIADRENERGIC AGENTS, CENTRALLY ACTING

Methyldopa

■ METHYLDOPA

methyldopa 250 mg tablet, 100

1629R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.28	21.53	^a Hydopa [AF]	
			^B 3.08	23.36	21.53	^a Aldomet [AS]	

Imidazoline receptor agonists

■ CLONIDINE

clonidine hydrochloride 150 microgram tablet, 100

3141H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.01	34.26	Catapres [BY]	

clonidine hydrochloride 100 microgram tablet, 100

3145M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	27.06	28.31	^a APO-Clonidine [TX]	^a Catapres 100 [BY]

■ GUANFACINE

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

9034

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a paediatrician or psychiatrist.

Clinical criteria:

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

Authority required (STREAMLINED)

9031

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

Authority required (STREAMLINED)

8544

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a paediatrician or psychiatrist.

Clinical criteria:

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must be receiving a maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine) which has been stable for at least four weeks, **AND**
- The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine), **AND**
- Patient must be experiencing residual moderate to severe ADHD symptoms resulting in impaired functioning (social, academic or occupational), present in at least one setting (home, nursery/school/college/work, friends or family homes or other environment).

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

Authority required (STREAMLINED)

8585

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine).

guanfacine 3 mg modified release tablet, 28

11440D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	124.11	40.30	Intuniv [ZI]

guanfacine 2 mg modified release tablet, 28

11451Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	124.11	40.30	Intuniv [ZI]

guanfacine 4 mg modified release tablet, 28

11441E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	124.11	40.30	Intuniv [ZI]

guanfacine 1 mg modified release tablet, 28

11452R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	124.11	40.30	Intuniv [ZI]

▪ **MOXONIDINE**

Restricted benefit

Hypertension

Clinical criteria:

- Patient must be receiving concurrent antihypertensive therapy.

moxonidine 400 microgram tablet, 30

9020R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	26.25	27.50	^a APO-Moxonidine [TX] ^a Moxonidine GX [SZ] ^a Physiotens [GO]	^a Moxonidine GH [GQ] ^a Moxonidine MYL [AF]

moxonidine 200 microgram tablet, 30

9019Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.15	21.40	^a APO-Moxonidine [TX] ^a Moxonidine GX [SZ] ^a Physiotens [GO]	^a Moxonidine GH [GQ] ^a Moxonidine MYL [AF]

ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING

Alpha-adrenoreceptor antagonists

▪ **PRazosin**

prazosin 1 mg tablet, 100

1479W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.61	16.86	^a APO-Prazosin [TX]	^a Minipress [PF]

prazosin 5 mg tablet, 100

1478T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.04	23.29	^a APO-Prazosin [TX]	^a Minipress [PF]

prazosin 2 mg tablet, 100

1480X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.36	18.61	^a APO-Prazosin [TX]	^a Minipress [PF]

ARTERIORAL SMOOTH MUSCLE, AGENTS ACTING ON*Hydrazinophthalazine derivatives***■ HYDRALAZINE****hydralazine hydrochloride 50 mg tablet, 100**

1639G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*20.41	21.66	Alphapress 50 [AF]

hydralazine hydrochloride 25 mg tablet, 100

1640H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*19.17	20.42	Alphapress 25 [AF]

*Pyrimidine derivatives***■ MINOXIDIL****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.

Restricted benefit

Severe refractory hypertension

Clinical criteria:

- The treatment must be initiated by a consultant physician.

minoxidil 10 mg tablet, 100

2313R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	51.24	40.30	Loniten [PF]

■ DIURETICS**LOW-CEILING DIURETICS, THIAZIDES***Thiazides, plain***■ HYDROCHLOROTHIAZIDE****hydrochlorothiazide 25 mg tablet, 100**

1484D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	21.95	23.20	Dithiazide [FF]

LOW-CEILING DIURETICS, EXCL. THIAZIDES*Sulfonamides, plain***■ CHLORTALIDONE****chlortalidone 25 mg tablet, 50**

1585K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*19.37	20.62	Hygroton 25 [GH]

■ INDAPAMIDE**indapamide hemihydrate 1.5 mg modified release tablet, 90**

8532C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	19.19	20.44	^a APO-Indapamide SR [TX]	^a INDAPAMIDE AN SR [EA]
				^b 7.15	26.34	^a Odaplix SR [AF]	^a Tenaxil SR [RW]
						^a Natrilix SR [SE]	

indapamide hemihydrate 2.5 mg tablet, 90

2436F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	16.76	18.01	^a Dapa-Tabs [AF]	^a GenRx Indapamide [GX]
				^b 7.58	24.34	^a Indapamide AN [EA]	^a Insig [RW]
						^a Natrilix [SE]	

HIGH-CEILING DIURETICS*Sulfonamides, plain*

■ FUROSEMIDE (FRUSEMIDE)

furosemide (frusemide) 40 mg tablet, 100

2412Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	13.16	14.41	Urex [RW] ^a APO-Frusemide [TX] ^a Frusax [ER] ^a Terry White Chemists Frusemide [TW]	^a Chem mart Frusemide [CH] ^a FUROSEMIDE AN [EA] ^a Uremide [AF]
			^B 2.40	15.56	14.41	^a Lasix [SW]	

furosemide (frusemide) 10 mg/mL oral liquid, 30 mL

2411X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	3	..	27.50	28.75	Lasix [SW]

furosemide (frusemide) 500 mg tablet, 50

2415D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	19.31	20.56	Urex-Forte [RW]

furosemide (frusemide) 20 mg/2 mL injection, 5 x 2 mL ampoules

2413B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.80	14.05	^a Frusemide-Clarix [BX] ^a Lasix [SW]	^a Frusemide Sandoz [SZ]

■ FUROSEMIDE (FRUSEMIDE)

Note For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.

furosemide (frusemide) 20 mg tablet, 100

2414C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	13.16	14.41	^a APO-Frusemide [TX] ^a FUROSEMIDE AN [EA]	^a Chem mart Frusemide [CH] ^a Terry White Chemists Frusemide [TW]

furosemide (frusemide) 20 mg tablet, 50

1810G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*13.17	14.42	^a Urex-M [RW]
			^B 2.40	*15.57	14.42	^a Lasix-M [SW]

Aryloxyacetic acid derivatives

■ ETACRYNIC ACID

Restricted benefit

Patients hypersensitive to other oral diuretics

etacrynic acid 25 mg tablet, 100

8748K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*152.43	40.30	Edecrin [FK]

POTASSIUM-SPARING AGENTS

Aldosterone antagonists

■ EPLERENONE

Caution Serum electrolytes should be checked regularly

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.

Authority required (STREAMLINED)

4937

Heart failure with a left ventricular ejection fraction of 40% or less

Clinical criteria:

- The condition must occur within 3 to 14 days following an acute myocardial infarction, **AND**
- The treatment must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

eplerenone 50 mg tablet, 30

8880J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	80.07	40.30	^a APO-Eplerenone [TX] ^a ESPLER [RW] ^a Inspra [PF]	^a Eplerenone AN [EA] ^a Inpler [AF]

eplerenone 25 mg tablet, 30

8879H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	80.07	40.30	^a APO-Eplerenone [TX]	^a Eplerenone AN [EA]
						^a ESPLER [RW]	^a Inpler [AF]
						^a Inspra [PF]	

■ SPIRONOLACTONE

Caution Serum electrolytes should be checked regularly

Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

spironolactone 25 mg tablet, 100

2339D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.50	17.75	^a Spiractin 25 [AF]
			^B 7.50	24.00	17.75	^a Aldactone [PF]

spironolactone 100 mg tablet, 100

2340E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	31.22	32.47	^a Spiractin 100 [AF]
			^B 7.49	38.71	32.47	^a Aldactone [PF]

DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION

Low-ceiling diuretics and potassium-sparing agents

■ AMILORIDE + HYDROCHLOROTHIAZIDE

Caution Serum electrolytes should be checked regularly.

amiloride hydrochloride dihydrate 5 mg + hydrochlorothiazide 50 mg tablet, 50

1486F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*17.65	18.90	Moduretic [AS]

OTHER DIURETICS

Vasopressin antagonists

■ TOLVAPTAN

Caution Tolvaptan has been associated with idiosyncratic hepatic toxicity. Liver function monitoring is required.

Authority required (STREAMLINED)

8288

Autosomal dominant polycystic kidney disease (ADPKD)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a nephrologist or in consultation with a nephrologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have end-stage renal disease defined as an estimated glomerular filtration rate (eGFR) of less than 15 mL/min/1.73m², **AND**
- Patient must not have had a kidney transplant.

tolvaptan 30 mg tablet [28] (&) tolvaptan 60 mg tablet [28], 56

11593E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1816.37	40.30	Jinarc [OS]

tolvaptan 30 mg tablet [28] (&) tolvaptan 90 mg tablet [28], 56

11596H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1816.37	40.30	Jinarc [OS]

tolvaptan 15 mg tablet [28] (&) tolvaptan 45 mg tablet [28], 56

11600M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1816.37	40.30	Jinarc [OS]

■ TOLVAPTAN

Caution Tolvaptan has been associated with idiosyncratic hepatic toxicity. Liver function monitoring is required.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Autosomal dominant polycystic kidney disease (ADPKD)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a nephrologist.

Clinical criteria:

- Patient must have an estimated glomerular filtration rate (eGFR) between 30 and 89 mL/min/1.73 m² at the initiation of treatment with this drug for this condition, **AND**
- Patient must have or have had rapidly progressing disease at the time of initiation of this drug for this condition. Rapidly progressing disease is defined as either of the following:

A decline in eGFR of greater than or equal to 5 mL/min/1.73 m² within one year;

OR

an average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 m² per year over a five year period.

Application for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Autosomal dominant polycystic kidney disease PBS Authority Application - Supporting Information Form which includes the following:
 - The eGFR at initiation of treatment; and
 - Confirmation that the patient has rapidly progressing disease or had rapidly progressing disease at the time treatment with this drug for this condition was initiated as defined as a decline in eGFR of greater than or equal to 5 mL/min/1.73 m² within one year or an average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 m² per year over a five year period.

tolvaptan 30 mg tablet [28] (&) tolvaptan 60 mg tablet [28], 56

11597J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1816.37	40.30	Jinarc [OS]

tolvaptan 30 mg tablet [28] (&) tolvaptan 90 mg tablet [28], 56

11588X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1816.37	40.30	Jinarc [OS]

tolvaptan 15 mg tablet [28] (&) tolvaptan 45 mg tablet [28], 56

11602P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1816.37	40.30	Jinarc [OS]

PERIPHERAL VASODILATORS**PERIPHERAL VASODILATORS**

Other peripheral vasodilators

PHENOXYBENZAMINE**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.

Restricted benefit

Phaeochromocytoma

Restricted benefit

Neurogenic urinary retention

phenoxybenzamine hydrochloride 10 mg capsule, 100

1862B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	948.46	40.30	Dibenyline [GH]

phenoxybenzamine hydrochloride 10 mg capsule, 100

9286R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	948.46	40.30	Dibenzyllyne [BZ]

phenoxybenzamine hydrochloride 10 mg capsule, 30

1166J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*854.11	40.30	Amdipharm Mercury (Australia) Pty Limited [GH]

BETA BLOCKING AGENTS**BETA BLOCKING AGENTS**

Beta blocking agents, non-selective

■ OXPRENOLOL

oxprenolol hydrochloride 40 mg tablet, 100

2961W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	41.79	40.30	Corbeton 40 [AF]

■ PINDOLOL

pindolol 5 mg tablet, 100

3062E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	32.36	33.61	Barbloc 5 [AF]

■ PROPRANOLOL

propranolol hydrochloride 40 mg tablet, 100

2566C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.50	15.75	^a APO-Propranolol [TX]
			^B 2.99	17.49	15.75	^a Deralin 40 [AF]
			^B 8.48	22.98	15.75	^a Inderal [AP]

propranolol hydrochloride 160 mg tablet, 50

2899N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.20	19.45	Deralin 160 [AF]

propranolol hydrochloride 10 mg tablet, 100

2565B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.23	15.48	^a APO-Propranolol [TX]
			^B 2.99	17.22	15.48	^a Deralin 10 [AF]
			^B 8.49	22.72	15.48	^a Inderal [AP]

Beta blocking agents, selective

■ ATENOLOL

atenolol 50 mg tablet, 30

1081X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.62	13.87	^a APO-Atenolol [TX]	^a Atenolol Amneal [EF]
						^a Atenolol-GA [ED]	^a Atenolol GH [GQ]
						^a Atenolol Sandoz [SZ]	^a Chem mart Atenolol [CH]
						^a Noten [AF]	^a Tenolten 50 [DO]
						^a Tensig [RW]	^a Terry White Chemists Atenolol [TW]
			^B 13.46	26.08	13.87	^a Tenormin [AP]	

■ ATENOLOL

Restricted benefit

For a patient who is unable to take a solid dose form of atenolol.

atenolol 50 mg/10 mL oral liquid, 300 mL

2243C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	29.76	31.01	Atenolol-AFT [AE]

■ BISOPROLOL

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.

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

bisoprolol fumarate 5 mg tablet, 28

8605X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.91	21.16	^a APO-Bisoprolol [TX]	^a Beprol 5 [DO]
						^a Bicard 5 [RW]	^a Bisoprolol AN [EA]
						^a Bisoprolol generichealth [GQ]	^a Bisoprolol Sandoz [SZ]
						^a Bispro 5 [AF]	^a Chem mart Bisoprolol [CH]
						^a Terry White Chemists Bisoprolol [TW]	
			^B 6.70	26.61	21.16	^a Bicar [AL]	

bisoprolol fumarate 10 mg tablet, 28

8606Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.02	23.27	^a APO-Bisoprolol [TX] ^a Bicard 10 [RW] ^a Bisoprolol generichealth [GQ] ^a Bispro 10 [AF] ^a Terry White Chemists Bisoprolol [TW]	^a Beprol 10 [DO] ^a Bisoprolol AN [EA] ^a Bisoprolol Sandoz [SZ] ^a Chem mart Bisoprolol [CH]
			^B 6.70	28.72	23.27	^a Bicolor [AL]	

bisoprolol fumarate 2.5 mg tablet, 28

8604W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.23	19.48	^a APO-Bisoprolol [TX] ^a Bicard 2.5 [RW] ^a Bisoprolol generichealth [GQ] ^a Bispro 2.5 [AF] ^a Terry White Chemists Bisoprolol [TW]	^a Beprol 2.5 [DO] ^a Bisoprolol AN [EA] ^a Bisoprolol Sandoz [SZ] ^a Chem mart Bisoprolol [CH]
			^B 6.70	24.93	19.48	^a Bicolor [AL]	

■ METOPROLOL SUCCINATE**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.

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30

8735R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	58.07	40.30	^a Metrol-XL 190 [RW] ^a Toprol-XL 190 [AP]	^a Minax XL [AF]

METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15

8732N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.80	19.05	^a Metrol-XL 23.75 [RW]	^a Minax XL [AF]

METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30

8734Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	48.75	40.30	^a Metrol-XL 95 [RW] ^a Toprol-XL 95 [AP]	^a Minax XL [AF]

METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30

8733P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.31	40.30	^a Metrol-XL 47.5 [RW] ^a Toprol-XL 47.5 [AP]	^a Minax XL [AF]

■ METOPROLOL TARTRATE**METOPROLOL TARTRATE Tablet 100 mg, 60**

1325R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.91	15.16	^a Metoprolol AN [EA] ^b APO-Metoprolol [TX] ^b Metoprolol Sandoz [SZ] ^b Minax 100 [AF]	^a Mistrom [ER] ^b Chem mart Metoprolol [CH] ^b Metrol 100 [RW] ^b Terry White Chemists Metoprolol [TW]
			^B 1.80	15.71	15.16	^a Lopresor 100 [NV]	
			^B 8.49	22.40	15.16	^b Betaloc [AP]	

METOPROLOL TARTRATE Tablet 50 mg, 100

1324Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.38	14.63	^a Metoprolol AN [EA] ^b APO-Metoprolol [TX] ^b Metoprolol Sandoz [SZ] ^b Minax 50 [AF]	^a Mistrom [ER] ^b Chem mart Metoprolol [CH] ^b Metrol 50 [RW] ^b Terry White Chemists Metoprolol [TW]
			^B 1.80	15.18	14.63	^a Lopresor 50 [NV]	
			^B 8.49	21.87	14.63	^b Betaloc [AP]	

■ NEBIVOLOL

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.

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

nebivolol 10 mg tablet, 28

9312D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	56.17	40.30	^a APO-Nebivolol [TX]	^a Nebilet [FK]

nebivolol 1.25 mg tablet, 28

9316H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*43.17	40.30	^a APO-Nebivolol [TX]	^a Nebilet [FK]

nebivolol 5 mg tablet, 28

9311C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	51.03	40.30	^a APO-Nebivolol [TX]	^a Nebilet [FK]

Alpha and beta blocking agents

■ CARVEDILOL

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.

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

Restricted benefit

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

carvedilol 3.125 mg tablet, 30

8255L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.52	15.77	^a APO-Carvedilol [TX] ^a Vedilol 3.125 [RW]	^a Carvedilol AN [EA] ^a Volirop 3.125 [DO]

carvedilol 12.5 mg tablet, 60

8257N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.25	23.50	^a APO-Carvedilol [TX] ^a Carvedilol Sandoz [SZ] ^a Dilatrend 12.5 [PB] ^a Volirop 12.5 [DO]	^a Carvedilol AN [EA] ^a Dicarz [AF] ^a Vedilol 12.5 [RW]

carvedilol 25 mg tablet, 60

8258P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.94	26.19	^a APO-Carvedilol [TX] ^a Carvedilol Sandoz [SZ] ^a Dilatrend 25 [PB] ^a Volirop 25 [DO]	^a Carvedilol AN [EA] ^a Dicarz [AF] ^a Vedilol 25 [RW]

carvedilol 6.25 mg tablet, 60

8256M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.09	21.34	^a APO-Carvedilol [TX] ^a Carvedilol Sandoz [SZ] ^a Dilatrend 6.25 [PB] ^a Volirop 6.25 [DO]	^a Carvedilol AN [EA] ^a Dicarz [AF] ^a Vedilol 6.25 [RW]

■ LABETALOL

labetalol hydrochloride 200 mg tablet, 100

1567L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.73	25.98	^a Presolol 200 [AF]
			^B 3.50	28.23	25.98	^a Trandate [QA]

labetalol hydrochloride 100 mg tablet, 100

1566K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.73	25.98	^a Presolol 100 [AF]
			^B 3.50	28.23	25.98	^a Trandate [QA]

■ CALCIUM CHANNEL BLOCKERS**SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS***Dihydropyridine derivatives***■ AMLODIPINE****amlodipine 5 mg tablet, 30**

2751T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.37	13.62	^a Amlo 5 [RW]	^a Amlodipine Amneal [EF]
						^a Amlodipine AN [EA]	^a Amlodipine APOTEX [GX]
						^a Amlodipine GH [GQ]	^a Amlodipine Sandoz [SZ]
						^a APO-Amlodipine [TX]	^a Auro-Amlodipine 5 [DO]
						^a Blooms the Chemist Amlodipine [IB]	^a BTC Amlodipine [JB]
						^a Chem mart Amlodipine [CH]	^a Nordip [AF]
						^a Norvapine [ED]	^a Pharmacor Amlodipine [CR]
						^a Terry White Chemists Amlodipine [TW]	
			^B 9.20	21.57	13.62	^a Norvasc [PF]	

amlodipine 10 mg tablet, 30

2752W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.06	14.31	^a Amlo 10 [RW]	^a Amlodipine Amneal [EF]
						^a Amlodipine AN [EA]	^a Amlodipine APOTEX [GX]
						^a Amlodipine GH [GQ]	^a Amlodipine Sandoz [SZ]
						^a APO-Amlodipine [TX]	^a Auro-Amlodipine 10 [DO]
						^a Blooms the Chemist Amlodipine [IB]	^a BTC Amlodipine [JB]
						^a Chem mart Amlodipine [CH]	^a Nordip [AF]
						^a Norvapine [ED]	^a Pharmacor Amlodipine [CR]
						^a Terry White Chemists Amlodipine [TW]	
			^B 9.20	22.26	14.31	^a Norvasc [PF]	

■ FELODIPINE**felodipine 10 mg modified release tablet, 30**

2367N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.78	20.03	^a Felodil XR 10 [RW]	^a Felodur ER 10 mg [TX]
						^a Fendex ER [AF]	
			^B 2.09	20.87	20.03	^a Plendil ER [GX]	

felodipine 2.5 mg modified release tablet, 30

2361G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.29	15.54	^a Felodur ER 2.5 mg [TX]	^a Fendex ER [AF]
			^B 2.08	16.37	15.54	^a Plendil ER [GX]	

felodipine 5 mg modified release tablet, 30

2366M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.51	16.76	^a Felodil XR 5 [RW]	^a Felodur ER 5 mg [TX]
						^a Fendex ER [AF]	
			^B 2.09	17.60	16.76	^a Plendil ER [GX]	

■ LERCANIDIPINE**lercanidipine hydrochloride 10 mg tablet, 28**

8534E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.58	14.83	^a APO-Lercanidipine [TX]	^a Blooms the Chemist Lercanidipine [IB]
						^a BTC Lercanidipine [JB]	^a Lercadip [EA]
						^a Lercan [RW]	^a Lercanidipine APOTEX [GX]
						^a Lercanidipine Sandoz [SZ]	^a Zircol 10 [AL]
			^B 3.50	17.08	14.83	^a Zanidip [GO]	

lercanidipine hydrochloride 20 mg tablet, 28

8679T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.97	16.22	^a APO-Lercanidipine [TX]	^a Blooms the Chemist Lercanidipine [IB]
						^a BTC Lercanidipine [JB]	^a Lercadip [EA]
						^a Lercan [RW]	^a Lercanidipine APOTEX [GX]
						^a Lercanidipine Sandoz [SZ]	^a Zircol 20 [AL]
			^B 3.50	18.47	16.22	^a Zanidip [GO]	

■ NIFEDIPINE**nifedipine 60 mg modified release tablet, 30**

1907J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.14	21.39	^a Addos XR 60 [RW]	^a Adefin XL 60 [AF]
						^a APO-Nifedipine XR [TX]	
			^B 4.81	24.95	21.39	^a Adalat Oros 60 [BN]	

nifedipine 30 mg modified release tablet, 30

1906H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.37	19.62	^a Addos XR 30 [RW]	^a Adefin XL 30 [AF]
						^a APO-Nifedipine XR [TX]	
			^B 4.67	23.04	19.62	^a Adalat Oros 30 [BN]	

nifedipine 20 mg tablet, 60

1695F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.62	18.87	Adefin 20 [AF]

nifedipine 20 mg modified release tablet, 30

8610E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.86	19.11	Adalat Oros 20mg [BN]

nifedipine 10 mg tablet, 60

1694E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.47	17.72	Adefin 10 [AF]

SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS*Phenylalkylamine derivatives***■ VERAPAMIL**

Caution The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

verapamil hydrochloride 180 mg modified release tablet, 30

2208F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.51	18.76	^a Cordilox 180 SR [GT]
			^B 3.50	21.01	18.76	^a Isoptin 180 SR [GO]

verapamil hydrochloride 80 mg tablet, 100

1250T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.95	20.20	^a Anpec 80 [AF]
			^B 3.50	22.45	20.20	^a Isoptin [GO]

verapamil hydrochloride 240 mg modified release tablet, 30

1241H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.52	20.77	^a Cordilox SR [GT]
			^B 3.50	23.02	20.77	^a Isoptin SR [GO]

verapamil hydrochloride 40 mg tablet, 100

1248Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.35	17.60	Anpec 40 [AF]

*Benzothiazepine derivatives***■ DILTIAZEM**

Caution The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

diltiazem hydrochloride 60 mg tablet, 90

1335G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.54	18.79	^a Diltiazem Actavis [ED]	^a Diltiazem AN [EA]
			^B 1.90	19.44	18.79	^a Cardizem [SW]	^a Vasocardol [AV]

diltiazem hydrochloride 180 mg modified release capsule, 30

1312C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	18.20	19.45	^a Diltiazem Sandoz CD [SZ]	^a Vasocardol CD [AV]

			^B 1.90	20.10	19.45	^a Cardizem CD [SW]	
NP	diltiazem hydrochloride 240 mg modified release capsule, 30						
1313D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.57	21.82	^a Diltiazem Sandoz CD [SZ]	^a Vasocardol CD [AV]
			^B 1.90	22.47	21.82	^a Cardizem CD [SW]	

diltiazem hydrochloride 360 mg modified release capsule, 30

8480H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.39	24.64	^a Diltiazem Sandoz CD [SZ]	^a Vasocardol CD [AV]
			^B 1.90	25.29	24.64	^a Cardizem CD [SW]	

AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

ACE INHIBITORS, PLAIN

ACE inhibitors, plain

■ CAPTOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

captopril 50 mg tablet, 90

1149L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	21.04	22.29	^a Captopril Sandoz [SZ]	
			^B 3.90	24.94	22.29	^a Capoten [RW]	
			^B 3.94	24.98	22.29	^a Zedace [AF]	

captopril 25 mg tablet, 90

1148K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	16.33	17.58	^a Captopril Sandoz [SZ]	
			^B 3.95	20.28	17.58	^a Zedace [AF]	
			^B 4.67	21.00	17.58	^a Capoten [RW]	

captopril 12.5 mg tablet, 90

1147J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	14.83	16.08	Captopril Sandoz [SZ]	

■ CAPTOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Patients unable to take a solid dose form of an ACE inhibitor.

captopril 5 mg/mL oral liquid, 95 mL

8760C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	‡1	5	..	107.30	40.30	Capoten [RW]	

■ ENALAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

enalapril maleate 10 mg tablet, 30

1368B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.57	15.82	^a Acetec [AL]	^a APO-Enalapril [TX]
						^a Enalapril Actavis [ED]	^a Enalapril generichealth [GQ]
						^a Enalapril Sandoz [SZ]	^a Malean [RW]
			^B 6.40	20.97	15.82	^a Renitec [MK]	

enalapril maleate 5 mg tablet, 30

1370D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.35	14.60	^a Acetec [AL]	^a APO-Enalapril [TX]
						^a Enalapril Actavis [ED]	^a Enalapril generichealth [GQ]
						^a Enalapril Sandoz [SZ]	^a Malean [RW]

enalapril maleate 20 mg tablet, 30

1369C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.40	16.65	^a Acetec [AL]	^a APO-Enalapril [TX]
						^a Enalapril Actavis [ED]	^a Enalapril generichealth [GQ]
						^a Enalapril Sandoz [SZ]	^a Malean [RW]
			^B 6.40	21.80	16.65	^a Renitec 20 [MK]	

■ FOSINOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

fosinopril sodium 20 mg tablet, 30

1183G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.19	19.44	^a APO-Fosinopril [TX] ^a Monace 20 [AF]	^a Fosipril 20 [RW]

fosinopril sodium 10 mg tablet, 30

1182F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.97	17.22	^a APO-Fosinopril [TX] ^a Monace 10 [AF]	^a Fosipril 10 [RW]

■ **LISINOPRIL**

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

lisinopril 5 mg tablet, 30

2456G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.64	14.89	^a APO-Lisinopril [TX] ^a Fibsol 5 [RW] ^a Lisinopril generichealth [GQ] ^a Zinopril 5 [AL]	^a Auro-Lisinopril 5 [DO] ^a Lisinopril AN [EA] ^a Lisinopril Sandoz [SZ]
			^B 4.84	18.48	14.89	^a Zestril [AP]	

lisinopril 20 mg tablet, 30

2458J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.56	16.81	^a APO-Lisinopril [TX] ^a Fibsol 20 [RW] ^a Lisinopril generichealth [GQ] ^a Zinopril 20 [AL]	^a Auro-Lisinopril 20 [DO] ^a Lisinopril AN [EA] ^a Lisinopril Sandoz [SZ]
			^B 4.83	20.39	16.81	^a Zestril [AP]	

lisinopril 10 mg tablet, 30

2457H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.72	15.97	^a APO-Lisinopril [TX] ^a Fibsol 10 [RW] ^a Lisinopril generichealth [GQ] ^a Zinopril 10 [AL]	^a Auro-Lisinopril 10 [DO] ^a Lisinopril AN [EA] ^a Lisinopril Sandoz [SZ]
			^B 4.83	19.55	15.97	^a Zestril [AP]	

■ **PERINDOPRIL**

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

perindopril erbumine 2 mg tablet, 30

3050M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.02	14.27	^a APO-Perindopril [TX] ^a Chem mart Perindopril [CH] ^a Indosyl Mono 2 [RW] ^a Perindopril Actavis 2 [EA] ^a Terry White Chemists Perindopril [TW]	^a Blooms the Chemist Perindopril [IB] ^a Idaprex 2 [SZ] ^a Perindo [AF] ^a Perindopril AN [EF]

perindopril arginine 2.5 mg tablet, 30

9006B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.02	14.27	^a APO-Perindopril Arginine [TX] ^B 7.32	^a PREXUM 2.5 [RW]
				20.34	14.27	^a Coversyl 2.5mg [SE]	

■ **PERINDOPRIL**

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 5 mg tablet are equivalent for the purposes of substitution.

perindopril arginine 5 mg tablet, 30

9007C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.34	15.59	^a APO-Perindopril Arginine [TX] ^B 7.01	^a PREXUM 5 [RW]
				21.35	15.59	^a Coversyl 5mg [SE]	

perindopril erbumine 4 mg tablet, 30

3051N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.34	15.59	^a APO-Perindopril [TX] ^a Chem mart Perindopril [CH]	^a Blooms the Chemist Perindopril [IB] ^a Idaprex 4 [SZ]

^a Indosyl Mono 4 [RW] ^a Perindo [AF]
^a Perindopril Actavis 4 [ED] ^a Perindopril AN [EF]
^a Perindopril generichealth [GQ] ^a Terry White Chemists Perindopril [TW]

■ PERINDOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril erbumine 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

perindopril erbumine 8 mg tablet, 30

8704D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.86	17.11	^a APO-Perindopril [TX]	^a Blooms the Chemist Perindopril [IB]
						^a Chem mart Perindopril [CH]	^a Idaprex 8 [SZ]
						^a Indosyl Mono 8 [RW]	^a Perindo [AF]
						^a Perindopril Actavis 8 [ED]	^a Perindopril AN [EF]
						^a Perindopril generichealth [GQ]	^a Terry White Chemists Perindopril [TW]

perindopril arginine 10 mg tablet, 30

9008D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.86	17.11	^a APO-Perindopril Arginine [TX]	^a PREXUM 10 [RW]
			^B 7.48	23.34	17.11	^a Coversyl 10mg [SE]	

■ QUINAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

quinapril 5 mg tablet, 30

1968N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.61	15.86	^a ACQUIN [RF]	^a Acquin Aspen 5 [RW]
						^a Qpril 5 [AF]	
			^B 4.20	18.81	15.86	^a Accupril [PF]	

quinapril 20 mg tablet, 30

1970Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.40	17.65	^a ACQUIN [RF]	^a Acquin Aspen 20 [RW]
						^a APO-Quinapril [TX]	^a Qpril 20 [AF]
						^a Quinapril generichealth [GQ]	
			^B 4.20	20.60	17.65	^a Accupril [PF]	

quinapril 10 mg tablet, 30

1969P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.47	16.72	^a ACQUIN [RF]	^a Acquin Aspen 10 [RW]
						^a APO-Quinapril [TX]	^a Qpril 10 [AF]
			^B 4.20	19.67	16.72	^a Accupril [PF]	

■ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.

ramipril 10 mg capsule, 30

8470T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.78	16.03	^a APO-Ramipril [TX]	^a Ramace 10 mg [AV]
						^a Ramipril AN [EA]	^a Ramipril Sandoz [SZ]
						^a Ramipril Winthrop [WA]	^a Tritace 10 mg [SW]
						^a Tryzan Caps 10 [AF]	

ramipril 10 mg tablet, 30

1316G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.78	16.03	^a APO-Ramipril [TX]	^a Ramipril AN [EA]
						^a Ramipril Sandoz [SZ]	^a Tritace [SW]
						^a Tryzan Tabs 10 [AF]	

■ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

ramipril 1.25 mg tablet, 30

1944H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.50	13.75	^a Ramace 1.25 mg [AV] ^a Ramipril Winthrop [WA] ^a Tryzan Tabs 1.25 [AF]	^a Ramipril Sandoz [SZ] ^a Tritace 1.25 mg [SW]

ramipril 1.25 mg capsule, 30

9120B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.50	13.75	^a APO-Ramipril [TX]	^a Tryzan Caps 1.25 [AF]

■ **RAMIPRIL**

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

ramipril 2.5 mg tablet, 30

1945J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.97	14.22	^a APO-Ramipril [TX] ^a Ramipril AN [EA] ^a Ramipril Winthrop [WA] ^a Tryzan Tabs 2.5 [AF]	^a Ramace 2.5 mg [AV] ^a Ramipril Sandoz [SZ] ^a Tritace 2.5 mg [SW]

ramipril 2.5 mg capsule, 30

9121C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.97	14.22	^a APO-Ramipril [TX]	^a Tryzan Caps 2.5 [AF]

■ **RAMIPRIL**

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

ramipril 5 mg tablet, 30

1946K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.35	14.60	^a APO-Ramipril [TX] ^a Ramipril AN [EA] ^a Ramipril Winthrop [WA] ^a Tryzan Tabs 5 [AF]	^a Ramace 5 mg [AV] ^a Ramipril Sandoz [SZ] ^a Tritace 5 mg [SW]

ramipril 5 mg capsule, 30

9122D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.35	14.60	^a APO-Ramipril [TX]	^a Tryzan Caps 5 [AF]

■ **TRANDOLAPRIL**

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

trandolapril 500 microgram capsule, 28

2791X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.59	14.84	^a Dolapril 0.5 [RW]	^a Tranalpha [AF]
			^B 3.50	17.09	14.84	^a Gopten [GO]	

trandolapril 2 mg capsule, 28

2793B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.26	17.51	^a Dolapril 2 [RW]	^a Tranalpha [AF]
			^B 3.50	19.76	17.51	^a Gopten [GO]	

trandolapril 1 mg capsule, 28

2792Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.45	16.70	^a Dolapril 1 [RW]	^a Tranalpha [AF]
			^B 3.50	18.95	16.70	^a Gopten [GO]	

trandolapril 4 mg capsule, 28

8758Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.47	21.72	^a Dolapril 4 [RW]	^a Tranalpha [AF]
			^B 3.49	23.96	21.72	^a Gopten [GO]	

ACE INHIBITORS, COMBINATIONS

ACE inhibitors and diuretics

■ **ENALAPRIL + HYDROCHLOROTHIAZIDE**

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30

8477E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.85	18.10	^a Enalapril/HCT Sandoz [SZ]
			^B 6.99	23.84	18.10	^a Renitec Plus 20/6 [MK]

■ FOSINOPRIL + HYDROCHLOROTHIAZIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

8401E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.88	21.13	^a APO-Fosinopril HCTZ 20/12.5 [TX]	^a Fosetic 20/12.5 [ZP]
						^a Fosinopril/HCT Actavis 20/12.5 [EA]	

■ PERINDOPRIL + INDAPAMIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30

2190G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	13.46	14.71	^a PREXUM Combi LD 2.5/0.625 [RW]
			^B 7.88	21.34	14.71	^a Coversyl Plus LD 2.5mg/0.625mg [SE]

■ PERINDOPRIL + INDAPAMIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide-like diuretic.

perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30

2845R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.22	16.47	^a Prexum Combi 5/1.25 [RW]
			^B 7.14	22.36	16.47	^a Coversyl Plus 5mg/1.25mg [SE]

perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30

8449Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.22	16.47	^a GenRx Perindopril/Indapamide 4/1.25 [GX]	^a Idaprex Combi 4/1.25 [SZ]
						^a Indosyl Combi 4/1.25 [RW]	^a Perindopril and Indapamide AN 4/1.25 [EF]
						^a Perindopril Combi Actavis 4/1.25 [ED]	^a Perindopril/ Indapamide GH 4/1.25 [GQ]
						^B 2.94	^a Perindo Combi 4/1.25 [AF]

■ QUINAPRIL + HYDROCHLOROTHIAZIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a thiazide diuretic.

quinapril 10 mg + hydrochlorothiazide 12.5 mg tablet, 30

8589C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.04	18.29	Accuretic 10/12.5mg [PF]

quinapril 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

8590D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.97	19.22	Accuretic 20/12.5mg [PF]

ACE inhibitors and calcium channel blockers

▪ **LERCANIDIPINE + ENALAPRIL**

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28

9144G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.46	17.71	Zan-Extra 10/10 [GO]

lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28

9145H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.24	18.49	Zan-Extra 10/20 [GO]

▪ **PERINDOPRIL + AMLODIPINE**

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

Restricted benefit

Stable coronary heart disease

Clinical criteria:

- The treatment must not be for the initiation of therapy for coronary heart disease, **AND**
- The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

perindopril arginine 5 mg + amlodipine 10 mg tablet, 30

9347Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.92	17.17	^a APO-Perindopril Arginine/Amlodipine 5/10 [TX]	^a Reaptan 5/10 [RW]
			^B 7.44	23.36	17.17	^a Coveram 5/10 [SE]	

perindopril arginine 5 mg + amlodipine 5 mg tablet, 30

9346X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.23	16.48	^a APO-Perindopril Arginine/Amlodipine 5/5 [TX]	^a Reaptan 5/5 [RW]
			^B 7.13	22.36	16.48	^a Coveram 5/5 [SE]	

perindopril arginine 10 mg + amlodipine 10 mg tablet, 30

9349C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.44	18.69	^a APO-Perindopril Arginine/Amlodipine 10/10 [TX]	^a Reaptan 10/10 [RW]
			^B 7.90	25.34	18.69	^a Coveram 10/10 [SE]	

perindopril arginine 10 mg + amlodipine 5 mg tablet, 30

9348B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.75	18.00	^a APO-Perindopril Arginine/Amlodipine 10/5 [TX]	^a Reaptan 10/5 [RW]
			^B 7.59	24.34	18.00	^a Coveram 10/5 [SE]	

▪ **RAMIPRIL + FELODIPINE**

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

ramipril 5 mg + felodipine 5 mg modified release tablet, 30

2629J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	17.38	18.63	Triasyn 5.0/5.0 [SW]	

ramipril 2.5 mg + felodipine 2.5 mg modified release tablet, 30

2626F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	15.78	17.03	Triasyn 2.5/2.5 [SW]	

■ TRANDOLAPRIL + VERAPAMIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero. The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an ACE inhibitor; OR
- The condition must be inadequately controlled with verapamil.

trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28

9387C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	21.90	23.15	Tarka 2/180 [GO]	

trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28

2857J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	27.97	29.22	Tarka 4/240 [GO]	

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN*Angiotensin II receptor blockers (ARBs), plain***■ CANDESARTAN****candesartan cilexetil 32 mg tablet, 30**

8889W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	16.47	17.72	^a Adesan [AF] ^a Blooms the Chemist Candesartan [IB] ^a Candesartan AN [EA] ^a Candesartan GH [GQ]	^a APO-Candesartan [TX] ^a CANDESAN [RF] ^a Candesartan Aspen 32 [RW] ^a Candesartan Sandoz [SZ]
			^B 13.47	29.94	17.72	^a Atacand [AP]	

candesartan cilexetil 4 mg tablet, 30

8295N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	11.94	13.19	^a Adesan [AF] ^a Blooms the Chemist Candesartan [IB] ^a Candesartan AN [EA] ^a Candesartan Sandoz [SZ]	^a APO-Candesartan [TX] ^a CANDESAN [RF] ^a Candesartan Aspen 4 [RW]
			^B 13.47	25.41	13.19	^a Atacand [AP]	

candesartan cilexetil 8 mg tablet, 30

8296P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	12.87	14.12	^a Adesan [AF] ^a Blooms the Chemist Candesartan [IB] ^a Candesartan AN [EA] ^a Candesartan Sandoz [SZ]	^a APO-Candesartan [TX] ^a CANDESAN [RF] ^a Candesartan Aspen 8 [RW]
			^B 13.47	26.34	14.12	^a Atacand [AP]	

candesartan cilexetil 16 mg tablet, 30

8297Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	15.61	16.86	^a Adesan [AF] ^a Blooms the Chemist Candesartan [IB] ^a Candesartan AN [EA]	^a APO-Candesartan [TX] ^a CANDESAN [RF] ^a Candesartan Aspen 16 [RW]

			^B 13.47	29.08	16.86	^a Atacand [AP]	^a Candesartan GH [GQ]	^a Candesartan Sandoz [SZ]

■ EPROSARTAN

eprosartan 400 mg tablet, 28

8397Y

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	5	^T 7.00	*30.85	25.10	Teveten [GO]

eprosartan 600 mg tablet, 28

8447N

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	^T 3.50	30.47	28.22	Teveten [GO]

■ EPROSARTAN

Authority required

Adverse effects occurring with all of the base-priced drugs

Authority required

Drug interactions occurring with all of the base-priced drugs

Authority required

Drug interactions expected to occur with all of the base-priced drugs

Authority required

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

eprosartan 400 mg tablet, 28

8951D

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	5	..	*30.85	32.10	Teveten [GO]

eprosartan 600 mg tablet, 28

5491B

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	30.47	31.72	Teveten [GO]

■ IRBESARTAN

irbesartan 300 mg tablet, 30

8248D

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	15.17	16.42	^a Abisart 300 [AL] ^a AVSARTAN [RF] ^a Chem mart Irbesartan [CH] ^a Irbesartan AMNEAL [EF] ^a Irbesartan GH [GQ] ^a Irprestan 300 [ZP] ^a APO-Irbesartan [TX] ^a Blooms the Chemist Irbesartan [IB] ^a Irbesartan Actavis 300 [ED] ^a Irbesartan AN [EA] ^a Irbesartan Sandoz [SZ] ^a Terry White Chemists Irbesartan [TW]	^a Abisart 300 [AL] ^a AVSARTAN [RF] ^a Chem mart Irbesartan [CH] ^a Irbesartan AMNEAL [EF] ^a Irbesartan GH [GQ] ^a Irprestan 300 [ZP] ^a APO-Irbesartan [TX] ^a Blooms the Chemist Irbesartan [IB] ^a Irbesartan Actavis 300 [ED] ^a Irbesartan AN [EA] ^a Irbesartan Sandoz [SZ] ^a Terry White Chemists Irbesartan [TW]
		^B 2.65	17.82	16.42	^a Avapro [AV] ^a Karvea [SW]	

irbesartan 75 mg tablet, 30

8246B

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	12.77	14.02	^a Abisart 75 [AL] ^a AVSARTAN [RF] ^a Chem mart Irbesartan [CH] ^a Irbesartan AMNEAL [EF] ^a Irbesartan GH [GQ] ^a Irprestan 75 [ZP] ^a APO-Irbesartan [TX] ^a Blooms the Chemist Irbesartan [IB] ^a Irbesartan Actavis 75 [ED] ^a Irbesartan AN [EA] ^a Irbesartan Sandoz [SZ] ^a Terry White Chemists Irbesartan [TW]	^a Abisart 75 [AL] ^a AVSARTAN [RF] ^a Chem mart Irbesartan [CH] ^a Irbesartan AMNEAL [EF] ^a Irbesartan GH [GQ] ^a Irprestan 75 [ZP] ^a APO-Irbesartan [TX] ^a Blooms the Chemist Irbesartan [IB] ^a Irbesartan Actavis 75 [ED] ^a Irbesartan AN [EA] ^a Irbesartan Sandoz [SZ] ^a Terry White Chemists Irbesartan [TW]
		^B 2.65	15.42	14.02	^a Avapro [AV] ^a Karvea [SW]	

irbesartan 150 mg tablet, 30

8247C

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	13.32	14.57	^a Abisart 150 [AL] ^a AVSARTAN [RF] ^a Chem mart Irbesartan [CH] ^a Irbesartan AMNEAL [EF] ^a Irbesartan GH [GQ] ^a Irprestan 150 [ZP] ^a APO-Irbesartan [TX] ^a Blooms the Chemist Irbesartan [IB] ^a Irbesartan Actavis 150 [ED] ^a Irbesartan AN [EA] ^a Irbesartan Sandoz [SZ] ^a Terry White Chemists Irbesartan [TW]	^a Abisart 150 [AL] ^a AVSARTAN [RF] ^a Chem mart Irbesartan [CH] ^a Irbesartan AMNEAL [EF] ^a Irbesartan GH [GQ] ^a Irprestan 150 [ZP] ^a APO-Irbesartan [TX] ^a Blooms the Chemist Irbesartan [IB] ^a Irbesartan Actavis 150 [ED] ^a Irbesartan AN [EA] ^a Irbesartan Sandoz [SZ] ^a Terry White Chemists Irbesartan [TW]
		^B 2.65	15.97	14.57	^a Avapro [AV] ^a Karvea [SW]	

■ **LOSARTAN****losartan potassium 50 mg tablet, 30**

8203R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*27.13	28.38	Cozavan [AF]

losartan potassium 25 mg tablet, 30

5452Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.95	18.20	Cozavan [AF]

■ **OLMESARTAN****olmesartan medoxomil 40 mg tablet, 30**

2148C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.38	22.63	^a APO-Olmesartan [TX] ^a Olmesartan AN [EA] ^a Olmesartan Sandoz [SZ]	^a OLMERTAN [RW] ^a Olmesartan - MYL [AF] ^a Pharmacor Olmesartan 40 [CR]
			^B 3.50	24.88	22.63	^a Olmetec [MK]	

olmesartan medoxomil 20 mg tablet, 30

2147B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.15	17.40	^a APO-Olmesartan [TX] ^a Olmesartan AN [EA] ^a Olmesartan Sandoz [SZ]	^a OLMERTAN [RW] ^a Olmesartan - MYL [AF] ^a Pharmacor Olmesartan 20 [CR]
			^B 3.50	19.65	17.40	^a Olmetec [MK]	

■ **TELMISARTAN****telmisartan 40 mg tablet, 28**

8355R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.25	14.50	^a APO-Telmisartan [TX] ^a Pharmacor Telmisartan 40 [CR] ^a Telmisartan-DRLA [RZ] ^a Telmisartan Sandoz [SZ]	^a Mizart [AF] ^a Telmisartan AN [EA] ^a Telmisartan GH [GQ] ^a Teltartan [RW]
			^B 3.77	17.02	14.50	^a Micardis [BY]	

telmisartan 80 mg tablet, 28

8356T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.62	17.87	^a APO-Telmisartan [TX] ^a Pharmacor Telmisartan 80 [CR] ^a Telmisartan-DRLA [RZ] ^a Telmisartan Sandoz [SZ]	^a Mizart [AF] ^a Telmisartan AN [EA] ^a Telmisartan GH [GQ] ^a Teltartan [RW]
			^B 3.76	20.38	17.87	^a Micardis [BY]	

■ **VALSARTAN****valsartan 40 mg tablet, 28**

9368C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	16.38	17.63	Diovan [NV]

valsartan 80 mg tablet, 28

9369D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.63	19.88	Diovan [NV]

valsartan 160 mg tablet, 28

9370E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	20.66	21.91	Diovan [NV]

■ **VALSARTAN**

Note No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

valsartan 320 mg tablet, 28

9371F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.25	24.50	Diovan [NV]

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), COMBINATIONS

Angiotensin II receptor blockers (ARBs) and diuretics

■ CANDESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30

9315G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.49	18.74	^a Adesan HCT 32/25 [AF]	^a APO-Candesartan HCTZ 32/25 [TX]
						^a Asartan HCT 32/25 [DO]	^a Blooms the Chemist Candesartan HCTZ 32/25 [IB]
						^a CANDESAN COMBI 32/25 [RF]	^a Candesartan Combi Aspen 32/25 [RW]
						^a Candesartan HCT GH 32/25 [GQ]	^a Candesartan/HCT Sandoz [SZ]
						^a Candesartan HCTZ AN 32/25 [EA]	
			^B 13.47	30.96	18.74	^a Atacand Plus 32/25 [AP]	

candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30

8504N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.91	17.16	^a Adesan HCT 16/12.5 [AF]	^a APO-Candesartan HCTZ 16/12.5 [TX]
						^a Asartan HCT 16/12.5 [DO]	^a Blooms the Chemist Candesartan HCTZ 16/12.5 [IB]
						^a CANDESAN COMBI 16/12.5 [RF]	^a Candesartan Combi Aspen 16/12.5 [RW]
						^a Candesartan HCT GH 16/12.5 [GQ]	^a Candesartan/HCT Sandoz [SZ]
						^a Candesartan HCTZ AN 16/12.5 [EA]	
			^B 13.47	29.38	17.16	^a Atacand Plus 16/12.5 [AP]	

candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30

9314F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.66	17.91	^a Adesan HCT 32/12.5 [AF]	^a APO-Candesartan HCTZ 32/12.5 [TX]
						^a Asartan HCT 32/12.5 [DO]	^a Blooms the Chemist Candesartan HCTZ 32/12.5 [IB]
						^a CANDESAN COMBI 32/12.5 [RF]	^a Candesartan Combi Aspen 32/12.5 [RW]
						^a Candesartan HCT GH 32/12.5 [GQ]	^a Candesartan/HCT Sandoz [SZ]
						^a Candesartan HCTZ AN 32/12.5 [EA]	
			^B 13.47	30.13	17.91	^a Atacand Plus 32/12.5 [AP]	

■ EPROSARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28

8624X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	28.45	29.70	Teveten Plus 600/12.5 [GO]

■ IRBESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

8404H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.59	14.84	^a Abisart HCTZ 150/12.5 [AL] ^a AVSARTAN HCT 150/12.5 [RF] ^a Chem mart Irbesartan HCTZ [CH] ^a Irbesartan HCT GH 150/12.5 [GQ] ^a Irbesartan HCTZ AMNEAL [EF] ^a Terry White Chemists Irbesartan HCTZ [TW]	^a APO-Irbesartan HCTZ [TX] ^a Blooms the Chemist Irbesartan HCTZ 150/12.5 [IB] ^a Irbesartan HCT Actavis 150/12.5 [ED] ^a Irbesartan/HCT Sandoz [SZ] ^a KSART HCT 150/12.5 [RW]
			^B 2.65	16.24	14.84	^a Avapro HCT 150/12.5 [AV]	^a Karvezide 150/12.5 [SW]

irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30

2136K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.69	16.94	^a Abisart HCTZ 300/25 [AL] ^a AVSARTAN HCT 300/25 [RF] ^a Chem mart Irbesartan HCTZ [CH] ^a Irbesartan HCT GH 300/25 [GQ] ^a Irbesartan HCTZ AMNEAL [EF] ^a Terry White Chemists Irbesartan HCTZ [TW]	^a APO-Irbesartan HCTZ [TX] ^a Blooms the Chemist Irbesartan HCTZ 300/25 [IB] ^a Irbesartan HCT Actavis 300/25 [ED] ^a Irbesartan/HCT Sandoz [SZ] ^a KSART HCT 300/25 [RW]
			^B 2.65	18.34	16.94	^a Avapro HCT 300/25 [AV]	^a Karvezide 300/25 [SW]

irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

8405J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.35	16.60	^a Abisart HCTZ 300/12.5 [AL] ^a AVSARTAN HCT 300/12.5 [RF] ^a Chem mart Irbesartan HCTZ [CH] ^a Irbesartan HCT GH 300/12.5 [GQ] ^a Irbesartan HCTZ AMNEAL [EF] ^a Terry White Chemists Irbesartan HCTZ [TW]	^a APO-Irbesartan HCTZ [TX] ^a Blooms the Chemist Irbesartan HCTZ 300/12.5 [IB] ^a Irbesartan HCT Actavis 300/12.5 [ED] ^a Irbesartan/HCT Sandoz [SZ] ^a KSART HCT 300/12.5 [RW]
			^B 2.65	18.00	16.60	^a Avapro HCT 300/12.5 [AV]	^a Karvezide 300/12.5 [SW]

■ OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE**Restricted benefit**

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30

2166B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.93	24.18	^a APO-Olmesartan/HCTZ 40/12.5 [TX] ^a Olmesartan HCT AN 40/12.5 [EA] ^a Olmesartan/HCT Sandoz [SZ]	^a OLMERTAN COMBI 40/12.5 [RW] ^a Olmesartan HCT - MYL 40/12.5 [AF] ^a Pharmacor Olmesartan HCTZ 40/12.5 [CR]
			^B 2.00	24.93	24.18	^a Olmetec Plus [MK]	

olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

2161R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.66	18.91	^a APO-Olmesartan/HCTZ 20/12.5 [TX] ^a Olmesartan HCT AN 20/12.5 [EA] ^a Olmesartan/HCT Sandoz [SZ]	^a OLMERTAN COMBI 20/12.5 [RW] ^a Olmesartan HCT - MYL 20/12.5 [AF] ^a Pharmacor Olmesartan HCTZ 20/12.5 [CR]
			^B 2.00	19.66	18.91	^a Olmetec Plus [MK]	

olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30

2170F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.43	25.68	^a APO-Olmesartan/HCTZ 40/25 [TX]	^a OLMERTAN COMBI 40/25 [RW]
						^a Olmesartan HCT AN 40/25 [EA]	^a Olmesartan HCT - MYL 40/25 [AF]
						^a Olmesartan/HCT Sandoz [SZ]	^a Pharmacor Olmesartan HCTZ 40/25 [CR]
			^b 2.00	26.43	25.68	^a Olmetec Plus [MK]	

■ **TELMISARTAN + HYDROCHLOROTHIAZIDE**

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28

9381R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.67	18.92	^a APO-Telmisartan HCTZ 80/25 [TX]	^a Mizart HCT 80/25 mg [AF]
						^a Telmisartan HCT GH 80/25 [GQ]	^a Telmisartan/HCT Sandoz [SZ]
						^a Telmisartan HCTZ AN 80/25 [EA]	^a Teltartan HCT 80/25 [RW]
			^b 3.77	21.44	18.92	^a Micardis Plus 80/25 mg [BY]	

telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

8623W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.17	18.42	^a APO-Telmisartan HCTZ 80/12.5 [TX]	^a Mizart HCT 80/12.5 mg [AF]
						^a Telmisartan HCT GH 80/12.5 [GQ]	^a Telmisartan/HCT Sandoz [SZ]
						^a Telmisartan HCTZ AN 80/12.5 [EA]	^a Teltartan HCT 80/12.5 [RW]
			^b 3.76	20.93	18.42	^a Micardis Plus 80/12.5 mg [BY]	

telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

8622T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.76	15.01	^a APO-Telmisartan HCTZ 40/12.5 [TX]	^a Mizart HCT 40/12.5 mg [AF]
						^a Telmisartan HCT GH 40/12.5 [GQ]	^a Telmisartan/HCT Sandoz [SZ]
						^a Telmisartan HCTZ AN 40/12.5 [EA]	^a Teltartan HCT 40/12.5 [RW]
			^b 3.76	17.52	15.01	^a Micardis Plus 40/12.5 mg [BY]	

■ **VALSARTAN + HYDROCHLOROTHIAZIDE**

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

9374J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	21.81	23.06	Co-Diovan 160/25 [NV]

valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

9373H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	20.73	21.98	Co-Diovan 160/12.5 [NV]

valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

9372G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.92	20.17	Co-Diovan 80/12.5 [NV]

■ **VALSARTAN + HYDROCHLOROTHIAZIDE**

Note No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28

9481B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.04	24.29	Co-Diovan 320/12.5 [NV]

valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

9482C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.11	25.36	Co-Diovan 320/25 [NV]

*Angiotensin II receptor blockers (ARBs) and calcium channel blockers***■ AMLODIPINE + VALSARTAN****Restricted benefit**

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

amlodipine 5 mg + valsartan 160 mg tablet, 28

9376L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	21.49	22.74	^a Valsartan/Amlodipine Novartis 160/5 [NM]
			^B 3.00	24.49	22.74	^a Exforge 5/160 [NV]

amlodipine 5 mg + valsartan 320 mg tablet, 28

5459H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.08	25.33	^a Valsartan/Amlodipine Novartis 320/5 [NM]
			^B 3.00	27.08	25.33	^a Exforge 5/320 [NV]

amlodipine 10 mg + valsartan 320 mg tablet, 28

5460J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.73	25.98	^a Valsartan/Amlodipine Novartis 320/10 [NM]
			^B 3.00	27.73	25.98	^a Exforge 10/320 [NV]

amlodipine 5 mg + valsartan 80 mg tablet, 28

9375K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.46	20.71	^a Valsartan/Amlodipine Novartis 80/5 [NM]
			^B 3.00	22.46	20.71	^a Exforge 5/80 [NV]

amlodipine 10 mg + valsartan 160 mg tablet, 28

9377M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	22.14	23.39	^a Valsartan/Amlodipine Novartis 160/10 [NM]
			^B 3.00	25.14	23.39	^a Exforge 10/160 [NV]

■ OLMESARTAN MEDOXOMIL + AMLODIPINE**Restricted benefit**

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30

5293N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.28	23.53	^a OLMEKAR [RW]	^a Olmesartan/Amlodipine 40/5 APOTEX [TX]
						^a Olmesartan/Amlodipine - MYL 40/5 [AF]	^a Sevikar 40/5 [AL]

olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30

5292M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.04	18.29	^a OLMEKAR [RW]	^a Olmesartan/Amlodipine 20/5 APOTEX [TX]
						^a Olmesartan/Amlodipine - MYL 20/5 [AF]	^a Sevikar 20/5 [AL]

olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30

5294P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.96	24.21	^a OLMEKAR [RW]	^a Olmesartan/Amlodipine 40/10 APOTEX [TX]
						^a Olmesartan/Amlodipine - MYL 40/10 [AF]	^a Sevikar 40/10 [AL]

▪ **TELMISARTAN + AMLODIPINE**

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

telmisartan 80 mg + amlodipine 10 mg tablet, 28

8981Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.09	19.34	^a Pritor/Amlodipine [FI]
			^B 3.77	21.86	19.34	^a Twynsta [BY]

telmisartan 40 mg + amlodipine 5 mg tablet, 28

8978M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.08	15.33	^a Pritor/Amlodipine [FI]
			^B 3.77	17.85	15.33	^a Twynsta [BY]

telmisartan 40 mg + amlodipine 10 mg tablet, 28

8979N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.73	15.98	^a Pritor/Amlodipine [FI]
			^B 3.76	18.49	15.98	^a Twynsta [BY]

telmisartan 80 mg + amlodipine 5 mg tablet, 28

8980P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.45	18.70	^a Pritor/Amlodipine [FI]
			^B 3.76	21.21	18.70	^a Twynsta [BY]

Angiotensin II receptor blockers (ARBs), other combinations

▪ **AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE**

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

5285E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.01	24.26	^a Valsartan/Amlodipine/HCT Novartis 160/5/12.5 [NM]
			^B 3.00	26.01	24.26	^a Exforge HCT 5/160/12.5 [NV]

amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

5287G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.65	24.90	^a Valsartan/Amlodipine/HCT Novartis 160/10/12.5 [NM]
			^B 3.00	26.65	24.90	^a Exforge HCT 10/160/12.5 [NV]

amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

5288H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	25.17	26.42	^a Valsartan/Amlodipine/HCT Novartis 160/10/25 [NM]
			^B 3.00	28.17	26.42	^a Exforge HCT 10/160/25 [NV]

amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

5286F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.52	25.77	^a Valsartan/Amlodipine/HCT Novartis 160/5/25 [NM]

			^B 3.00	27.52	25.77	^a Exforge HCT 5/160/25 [NV]
amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28						
5289J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	1	5	..	27.76	29.01	^a Valsartan/Amlodipine/HCT Novartis 320/10/25 [NM]
			^B 3.00	30.76	29.01	^a Exforge HCT 10/320/25 [NV]

■ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30

2836G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	1	5	..	24.53	25.78	Sevikar HCT 40/10/12.5 [MK]

olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

2880N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	1	5	..	23.84	25.09	Sevikar HCT 40/5/12.5 [MK]

olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

10005N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	1	5	..	18.61	19.86	Sevikar HCT 20/5/12.5 [MK]

olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30

2864R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	1	5	..	25.41	26.66	Sevikar HCT 40/5/25 [MK]

olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30

2953K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	1	5	..	26.10	27.35	Sevikar HCT 40/10/25 [MK]

■ SACUBITRIL + VALSARTAN

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 Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6915

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56

11131W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	1	5	..	198.25	40.30	Entresto [NV]

sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56

11123K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	1	5	..	198.25	40.30	Entresto [NV]

sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56

11122J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	1	5	..	198.25	40.30	Entresto [NV]

■ **LIPID MODIFYING AGENTS**

LIPID MODIFYING AGENTS, PLAIN

HMG CoA reductase inhibitors

■ **ATORVASTATIN**

atorvastatin 20 mg tablet, 30

8214H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.74	14.99	^a APO-Atorvastatin [TX] ^a Atorvastatin Amneal [EF] ^a Atorvastatin Sandoz [SZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lorstat 20 [AF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [RF] ^a Atorvastatin GH [GQ] ^a Atorvastatin SZ [HX] ^a Lipitor [PF] ^a Pharmacor Atorvastatin [CR] ^a Torvastat 20 [RW]

atorvastatin 40 mg tablet, 30

8215J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.65	15.90	^a APO-Atorvastatin [TX] ^a Atorvastatin Amneal [EF] ^a Atorvastatin Sandoz [SZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lorstat 40 [AF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [RF] ^a Atorvastatin GH [GQ] ^a Atorvastatin SZ [HX] ^a Lipitor [PF] ^a Pharmacor Atorvastatin [CR] ^a Torvastat 40 [RW]

atorvastatin 10 mg tablet, 30

8213G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.01	14.26	^a APO-Atorvastatin [TX] ^a Atorvastatin Amneal [EF] ^a Atorvastatin Sandoz [SZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lorstat 10 [AF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [RF] ^a Atorvastatin GH [GQ] ^a Atorvastatin SZ [HX] ^a Lipitor [PF] ^a Pharmacor Atorvastatin [CR] ^a Torvastat 10 [RW]

atorvastatin 80 mg tablet, 30

8521L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.02	17.27	^a APO-Atorvastatin [TX] ^a Atorvastatin GH [GQ] ^a Atorvastatin SZ [HX] ^a Lipitor [PF] ^a Pharmacor Atorvastatin [CR] ^a Torvastat 80 [RW]	^a Atorvastatin Amneal [EF] ^a Atorvastatin Sandoz [SZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lorstat 80 [AF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]

■ **ATORVASTATIN**

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

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

Restricted benefit

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

atorvastatin 20 mg tablet, 30

9231W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.74	14.99	^a APO-Atorvastatin [TX] ^a Atorvastatin Amneal [EF] ^a Atorvastatin Sandoz [SZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lorstat 20 [AF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [RF] ^a Atorvastatin GH [GQ] ^a Atorvastatin SZ [HX] ^a Lipitor [PF] ^a Pharmacor Atorvastatin [CR] ^a Torvastat 20 [RW]

atorvastatin 40 mg tablet, 30

9232X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.65	15.90	^a APO-Atorvastatin [TX] ^a Atorvastatin Amneal [EF] ^a Atorvastatin Sandoz [SZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lorstat 40 [AF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [RF] ^a Atorvastatin GH [GQ] ^a Atorvastatin SZ [HX] ^a Lipitor [PF] ^a Pharmacor Atorvastatin [CR] ^a Torvastat 40 [RW]

atorvastatin 10 mg tablet, 30

9230T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.01	14.26	^a APO-Atorvastatin [TX] ^a Atorvastatin Amneal [EF] ^a Atorvastatin Sandoz [SZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lorstat 10 [AF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [RF] ^a Atorvastatin GH [GQ] ^a Atorvastatin SZ [HX] ^a Lipitor [PF] ^a Pharmacor Atorvastatin [CR] ^a Torvastat 10 [RW]

atorvastatin 80 mg tablet, 30

9233Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	16.02	17.27	^a APO-Atorvastatin [TX] ^a Atorvastatin GH [GQ] ^a Atorvastatin SZ [HX] ^a Lipitor [PF] ^a Pharmacor Atorvastatin [CR] ^a Torvastat 80 [RW]	^a Atorvastatin Amneal [EF] ^a Atorvastatin Sandoz [SZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lorstat 80 [AF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]

FLUVASTATIN**fluvastatin 80 mg modified release tablet, 28**

2863Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	45.98	40.30	Lescol XL [NV]

FLUVASTATIN

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

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

Restricted benefit

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

fluvastatin 80 mg modified release tablet, 28

9236D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	11	..	45.98	40.30	Lescol XL [NV]

PRAVASTATIN**pravastatin sodium 80 mg tablet, 30**

8829Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	17.32	18.57	^a APO-Pravastatin [TX] ^a Pravastatin AN [EA] ^a Pravastatin Sandoz [SZ]	^a Lipostat 80 [RF] ^a Pravastatin generichealth [GQ]
			^B 3.01	20.33	18.57	^a Pravachol [RW]	

pravastatin sodium 40 mg tablet, 30

8197K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	15.28	16.53	^a APO-Pravastatin [TX] ^a Lipostat 40 [RF] ^a Pravastatin Sandoz [SZ]	^a Cholstat 40 [AF] ^a Pravastatin AN [EA]
			^B 3.01	18.29	16.53	^a Pravachol [RW]	

pravastatin sodium 20 mg tablet, 30

2834E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	13.92	15.17	^a APO-Pravastatin [TX] ^a Lipostat 20 [RF]	^a Cholstat 20 [AF] ^a Pravastatin AN [EA]

						^a Pravastatin generichealth [GQ]	^a Pravastatin Sandoz [SZ]
			^B 2.96	16.88	15.17	^a Pravachol [RW]	
pravastatin sodium 10 mg tablet, 30							
2833D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	13.02	14.27	^a APO-Pravastatin [TX]	^a Lipostat 10 [RF]
						^a Pravastatin AN [EA]	^a Pravastatin generichealth [GQ]
						^a Pravastatin Sandoz [SZ]	
			^B 2.94	15.96	14.27	^a Pravachol [RW]	
			^B 2.95	15.97	14.27	^a Cholstat 10 [AF]	

■ PRAVASTATIN

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

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

Restricted benefit

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

pravastatin sodium 80 mg tablet, 30

9240H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	17.32	18.57	^a APO-Pravastatin [TX]	^a Lipostat 80 [RF]
						^a Pravastatin AN [EA]	^a Pravastatin generichealth [GQ]
						^a Pravastatin Sandoz [SZ]	
			^B 3.01	20.33	18.57	^a Pravachol [RW]	

pravastatin sodium 40 mg tablet, 30

9239G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	15.28	16.53	^a APO-Pravastatin [TX]	^a Cholstat 40 [AF]
						^a Lipostat 40 [RF]	^a Pravastatin AN [EA]
						^a Pravastatin Sandoz [SZ]	
			^B 3.01	18.29	16.53	^a Pravachol [RW]	

pravastatin sodium 20 mg tablet, 30

9238F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.92	15.17	^a APO-Pravastatin [TX]	^a Cholstat 20 [AF]
						^a Lipostat 20 [RF]	^a Pravastatin AN [EA]
						^a Pravastatin generichealth [GQ]	^a Pravastatin Sandoz [SZ]
			^B 2.96	16.88	15.17	^a Pravachol [RW]	

pravastatin sodium 10 mg tablet, 30

9237E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.02	14.27	^a APO-Pravastatin [TX]	^a Lipostat 10 [RF]
						^a Pravastatin AN [EA]	^a Pravastatin generichealth [GQ]
						^a Pravastatin Sandoz [SZ]	
			^B 2.94	15.96	14.27	^a Pravachol [RW]	
			^B 2.95	15.97	14.27	^a Cholstat 10 [AF]	

■ ROSUVASTATIN

rosuvastatin 10 mg tablet, 30

2628H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	17.01	18.26	^a APO-Rosuvastatin [TX]	^a Blooms the Chemist Rosuvastatin [IB]
						^a BTC Rosuvastatin [JB]	^a Cavstat [AF]
						^a Chem mart Rosuvastatin [CH]	^a Crosuva 10 [RW]
						^a Noumed Rosuvastatin [VO]	^a Pharmacor Rosuvastatin 10 [CR]
						^a Rostor 10 [DO]	^a Rosuvastatin AMNEAL [EF]
						^a Rosuvastatin APOTEX [GX]	^a Rosuvastatin-DRLA [RI]
						^a Rosuvastatin generichealth [HQ]	^a Rosuvastatin RBX [RA]
						^a Rosuvastatin Sandoz [SZ]	^a Terry White Chemists Rosuvastatin [TW]
			^B 2.15	19.16	18.26	^a Crestor [AP]	

rosuvastatin 40 mg tablet, 30

2594M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	22.69	23.94	^a APO-Rosuvastatin [TX]	^a Blooms the Chemist Rosuvastatin [IB]
						^a BTC Rosuvastatin [JB]	^a Cavstat [AF]
						^a Chem mart Rosuvastatin [CH]	^a Crosuva 40 [RW]
						^a Noumed Rosuvastatin [VO]	^a Pharmacor Rosuvastatin 40 [CR]

^a Rostor 40 [DO]	^a Rosuvastatin AMNEAL [EF]
^a Rosuvastatin APOTEX [GX]	^a Rosuvastatin-DRLA [RI]
^a Rosuvastatin generichealth [HQ]	^a Rosuvastatin RBX [RA]
^a Rosuvastatin Sandoz [SZ]	^a Terry White Chemists Rosuvastatin [TW]

^B3.12 25.81 23.94 ^a Crestor [AP]

rosuvastatin 20 mg tablet, 30

2574L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.34	20.59	^a APO-Rosuvastatin [TX]	^a Blooms the Chemist Rosuvastatin [IB]
						^a BTC Rosuvastatin [JB]	^a Cavstat [AF]
						^a Chem mart Rosuvastatin [CH]	^a Crosuva 20 [RW]
						^a Noumed Rosuvastatin [VO]	^a Pharmacor Rosuvastatin 20 [CR]
						^a Rostor 20 [DO]	^a Rosuvastatin AMNEAL [EF]
						^a Rosuvastatin APOTEX [GX]	^a Rosuvastatin-DRLA [RI]
						^a Rosuvastatin generichealth [HQ]	^a Rosuvastatin RBX [RA]
						^a Rosuvastatin Sandoz [SZ]	^a Terry White Chemists Rosuvastatin [TW]
			^B 2.15	21.49	20.59	^a Crestor [AP]	

rosuvastatin 5 mg tablet, 30

2606E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.24	16.49	^a APO-Rosuvastatin [TX]	^a Blooms the Chemist Rosuvastatin [IB]
						^a BTC Rosuvastatin [JB]	^a Cavstat [AF]
						^a Chem mart Rosuvastatin [CH]	^a Crosuva 5 [RW]
						^a Noumed Rosuvastatin [VO]	^a Pharmacor Rosuvastatin 5 [CR]
						^a Rostor 5 [DO]	^a Rosuvastatin AMNEAL [EF]
						^a Rosuvastatin APOTEX [GX]	^a Rosuvastatin-DRLA [RI]
						^a Rosuvastatin generichealth [HQ]	^a Rosuvastatin RBX [RA]
						^a Rosuvastatin Sandoz [SZ]	^a Terry White Chemists Rosuvastatin [TW]
			^B 2.15	17.39	16.49	^a Crestor [AP]	

■ ROSUVASTATIN

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

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

Restricted benefit

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

rosuvastatin 10 mg tablet, 30

2584B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	17.01	18.26	^a APO-Rosuvastatin [TX]	^a Blooms the Chemist Rosuvastatin [IB]
						^a BTC Rosuvastatin [JB]	^a Cavstat [AF]
						^a Chem mart Rosuvastatin [CH]	^a Crosuva 10 [RW]
						^a Noumed Rosuvastatin [VO]	^a Pharmacor Rosuvastatin 10 [CR]
						^a Rostor 10 [DO]	^a Rosuvastatin AMNEAL [EF]
						^a Rosuvastatin APOTEX [GX]	^a Rosuvastatin-DRLA [RI]
						^a Rosuvastatin generichealth [HQ]	^a Rosuvastatin RBX [RA]
						^a Rosuvastatin Sandoz [SZ]	^a Terry White Chemists Rosuvastatin [TW]
			^B 2.15	19.16	18.26	^a Crestor [AP]	

rosuvastatin 40 mg tablet, 30

2636R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	22.69	23.94	^a APO-Rosuvastatin [TX]	^a Blooms the Chemist Rosuvastatin [IB]
						^a BTC Rosuvastatin [JB]	^a Cavstat [AF]
						^a Chem mart Rosuvastatin [CH]	^a Crosuva 40 [RW]
						^a Noumed Rosuvastatin [VO]	^a Pharmacor Rosuvastatin 40 [CR]
						^a Rostor 40 [DO]	^a Rosuvastatin AMNEAL [EF]
						^a Rosuvastatin APOTEX [GX]	^a Rosuvastatin-DRLA [RI]

^a Rosuvastatin generichealth [HQ]
^a Rosuvastatin Sandoz [SZ]
^a Rosuvastatin RBX [RA]
^a Terry White Chemists Rosuvastatin [TW]
^B3.12 25.81 23.94 ^a Crestor [AP]

rosuvastatin 20 mg tablet, 30

2609H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	19.34	20.59	^a APO-Rosuvastatin [TX] ^a BTC Rosuvastatin [JB] ^a Chem mart Rosuvastatin [CH] ^a Noumed Rosuvastatin [VO] ^a Rostor 20 [DO] ^a Rosuvastatin APOTEX [GX] ^a Rosuvastatin generichealth [HQ] ^a Rosuvastatin Sandoz [SZ]	^a Blooms the Chemist Rosuvastatin [IB] ^a Cavstat [AF] ^a Crosuva 20 [RW] ^a Pharmacor Rosuvastatin 20 [CR] ^a Rosuvastatin AMNEAL [EF] ^a Rosuvastatin-DRLA [RI] ^a Rosuvastatin RBX [RA] ^a Terry White Chemists Rosuvastatin [TW]
			^B 2.15	21.49	20.59	^a Crestor [AP]	

rosuvastatin 5 mg tablet, 30

2590H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	15.24	16.49	^a APO-Rosuvastatin [TX] ^a BTC Rosuvastatin [JB] ^a Chem mart Rosuvastatin [CH] ^a Noumed Rosuvastatin [VO] ^a Rostor 5 [DO] ^a Rosuvastatin APOTEX [GX] ^a Rosuvastatin generichealth [HQ] ^a Rosuvastatin Sandoz [SZ]	^a Blooms the Chemist Rosuvastatin [IB] ^a Cavstat [AF] ^a Crosuva 5 [RW] ^a Pharmacor Rosuvastatin 5 [CR] ^a Rosuvastatin AMNEAL [EF] ^a Rosuvastatin-DRLA [RI] ^a Rosuvastatin RBX [RA] ^a Terry White Chemists Rosuvastatin [TW]
			^B 2.15	17.39	16.49	^a Crestor [AP]	

■ SIMVASTATIN**simvastatin 40 mg tablet, 30**

8173E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	13.81	15.06	^a APO-Simvastatin [TX] ^a Simvar 40 [RW] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]	^a Chem mart Simvastatin [CH] ^a Simvastatin AN [EA] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]
			^B 7.50	21.31	15.06	^a Lipex 40 [FR]	^a Zocor [MK]

simvastatin 80 mg tablet, 30

8313M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	14.81	16.06	^a APO-Simvastatin [TX] ^a Ransim [RA] ^a Simvastatin AN [EA] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]	^a Chem mart Simvastatin [CH] ^a Simvar 80 [RW] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]
			^B 8.46	23.27	16.06	^a Lipex 80 [FR]	^a Zocor [MK]

simvastatin 10 mg tablet, 30

2011W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	12.60	13.85	^a APO-Simvastatin [TX] ^a Ransim [RA] ^a Simvastatin AN [EA] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]	^a Chem mart Simvastatin [CH] ^a Simvar 10 [RW] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]
			^B 5.33	17.93	13.85	^a Lipex 10 [FR]	^a Zocor [MK]

simvastatin 5 mg tablet, 30

2013Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.30	13.55	^a Simvastatin Sandoz [SZ]	^a Zimstat [AF]

simvastatin 20 mg tablet, 30

2012X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.10	14.35	^a APO-Simvastatin [TX] ^a Simvar 20 [RW] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]	^a Chem mart Simvastatin [CH] ^a Simvastatin AN [EA] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]
			^B 7.50	20.60	14.35	^a Lipex 20 [FR]	^a Zocor [MK]

■ SIMVASTATIN

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

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

Restricted benefit

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

simvastatin 40 mg tablet, 30

9244M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.81	15.06	^a APO-Simvastatin [TX] ^a Simvar 40 [RW] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]	^a Chem mart Simvastatin [CH] ^a Simvastatin AN [EA] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]
			^B 7.50	21.31	15.06	^a Lipex 40 [FR]	^a Zocor [MK]

simvastatin 80 mg tablet, 30

9245N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.81	16.06	^a APO-Simvastatin [TX] ^a Ransim [RA] ^a Simvastatin AN [EA] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]	^a Chem mart Simvastatin [CH] ^a Simvar 80 [RW] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]
			^B 8.46	23.27	16.06	^a Lipex 80 [FR]	^a Zocor [MK]

simvastatin 10 mg tablet, 30

9242K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	12.60	13.85	^a APO-Simvastatin [TX] ^a Ransim [RA] ^a Simvastatin AN [EA] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]	^a Chem mart Simvastatin [CH] ^a Simvar 10 [RW] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]
			^B 5.33	17.93	13.85	^a Lipex 10 [FR]	^a Zocor [MK]

simvastatin 5 mg tablet, 30

9241J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	12.30	13.55	^a Simvastatin Sandoz [SZ]	^a Zimstat [AF]

simvastatin 20 mg tablet, 30

9243L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.10	14.35	^a APO-Simvastatin [TX] ^a Simvar 20 [RW] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]	^a Chem mart Simvastatin [CH] ^a Simvastatin AN [EA] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]
			^B 7.50	20.60	14.35	^a Lipex 20 [FR]	^a Zocor [MK]

Fibrates**■ FENOFIBRATE**

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high

cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

fenofibrate 145 mg tablet, 30

9023X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	31.25	32.50	^a Fenocol [YC] ^a Fenofibrate Mylan [AF] ^a Lipidil [GO]	^a Fenofibrate Cipla [LR] ^a FENOFIBRATE RBX [RA]

fenofibrate 48 mg tablet, 60

9022W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.66	25.91	^a Fenofibrate Mylan [AF] ^a Lipidil [GO]	^a FENOFIBRATE RBX [RA]

▪ **FENOFIBRATE**

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

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

Restricted benefit

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

fenofibrate 145 mg tablet, 30

9247Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	31.25	32.50	^a Fenocol [YC] ^a Fenofibrate Mylan [AF] ^a Lipidil [GO]	^a Fenofibrate Cipla [LR] ^a FENOFIBRATE RBX [RA]

fenofibrate 48 mg tablet, 60

9246P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	24.66	25.91	^a Fenofibrate Mylan [AF] ^a Lipidil [GO]	^a FENOFIBRATE RBX [RA]

▪ **GEMFIBROZIL**

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

gemfibrozil 600 mg tablet, 60

1453L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.38	22.63	^a Ausgem [RW]	^a Lipigem [AF]

▪ **GEMFIBROZIL**

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

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

Restricted benefit

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

gemfibrozil 600 mg tablet, 60

9248R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	21.38	22.63	^a Ausgem [RW]	^a Lipigem [AF]

Bile acid sequestrants

▪ **COLESTYRAMINE**

colestyramine 4 g powder for oral liquid, 50 sachets

2967E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*80.91	40.30	Questran Lite [QA]

▪ **COLESTYRAMINE**

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

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

Restricted benefit

Primary hypercholesterolaemia

Clinical criteria:

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

colestyramine 4 g powder for oral liquid, 50 sachets

9249T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	11	..	*80.91	40.30	Questran Lite [QA]

Other lipid modifying agents**■ EVOLOCUMAB**

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

Note Special Pricing Arrangements apply.

Authority required

Familial homozygous hypercholesterolaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, **AND**
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin or rosuvastatin according to the TGA-approved Product Information for at least 3 months in conjunction with dietary therapy and exercise; OR
- Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information.

Treatment criteria:

- Must be treated by a specialist physician.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

The date of the consultation with a specialist physician must be no more than 6 months prior to the application date. The full name of the specialist physician consulted and the date of consultation are to be provided at the time of application.

The qualifying LDL cholesterol level must be provided at the time of application and must be no more than 2 months old.

The physician must attempt to treat the patient with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily).

With the exception of the situation where the patient is contraindicated to treatment with a statin, the agent, dose and duration of statin treatment must be provided at the time of application.

Contraindication to treatment with a statin is as defined in the TGA-approved Product Information.

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

- A completed authority prescription form; and
- A completed Familial homozygous hypercholesterolaemia Initial PBS Authority Application - Supporting Information Form; and
- The date of consultation and the full name of the specialist physician; and
- A copy of the qualifying Dutch Lipid Clinic Network Score or a copy of the result of genetic testing; and
- The result of LDL cholesterol level and one of the following where appropriate: statin treatment details including agent, dose and treatment duration; or details of adverse event or contraindication to treatment with a statin as defined in the TGA-approved Product Information.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Familial homozygous hypercholesterolaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge

11193D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	683.24	40.30	Repatha [AN]

evolocumab 140 mg/mL injection, 1 mL pen device

10958R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*943.54	40.30	Repatha [AN]

■ EVOLOCUMAB

Note No 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

Familial heterozygous hypercholesterolaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have an LDL cholesterol level in excess of 3.3 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR
- Patient must have an LDL cholesterol level in excess of 5 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin or rosuvastatin according to the TGA-approved Product Information for at least 3 months in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 3 months in conjunction with dietary therapy and exercise.

Treatment criteria:

- Must be treated by a specialist physician.

A clinically important product-related adverse event is defined as follows:

- Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Symptomatic atherosclerotic cardiovascular disease is defined as:

- the presence of symptomatic coronary artery disease; or
- the presence of symptomatic cerebrovascular disease; or
- the presence of symptomatic peripheral vascular disease.

The date of the consultation with a specialist physician must be no more than 6 months prior to the application date. The full name of the specialist physician consulted and the date of consultation are to be provided at the time of application.

The qualifying LDL cholesterol level must be provided at the time of application and must be no more than 2 months old.

The physician must attempt to treat the patient with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily).

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin). This retreatment should occur after a washout period of at least 1 month, or if the creatine kinase (CK) level is elevated retreatment should not occur until CK has returned to normal.

In the event of a trial of an alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the maximum tolerated dose has been reached or target LDL-c has been achieved.

At the time of application, one of the following must be provided:

- Confirmation that the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg for 3 months; or
- The doses and duration of treatment and adverse events experienced with trials with each of atorvastatin and rosuvastatin; or
- Confirmation that the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

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

- A completed authority prescription form; and

- b) A completed Familial heterozygous hypercholesterolaemia Initial PBS Authority Application - Supporting Information Form; and
- c) The date of consultation and the full name of the specialist physician; and
- d) A copy of the qualifying Dutch Lipid Clinic Network Score or a copy of the result of genetic testing; and
- e) The result of LDL cholesterol level and one of the following where appropriate: statin treatment details including agent, dose and treatment duration; or details of adverse events to each of atorvastatin and rosuvastatin or contraindication to treatment with a statin as defined in the TGA-approved Product Information.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Familial heterozygous hypercholesterolaemia

Treatment Phase: Grandfather treatment

Clinical criteria:

- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 November 2018, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have had an LDL cholesterol level in excess of 3.3 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS subsidised treatment with this drug for this condition was initiated; OR
- Patient must have had an LDL cholesterol level in excess of 5 millimoles per litre at the time non-PBS subsidised treatment with this drug for this condition was initiated, **AND**
- Patient must have been treated with the maximum tolerated dose of atorvastatin or rosuvastatin according to the TGA-approved Product Information for at least 3 months in conjunction with dietary therapy and exercise prior to initiating non-PBS subsidised treatment with this drug for this condition; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information.

Treatment criteria:

- Must be treated by a specialist physician.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease; or

(ii) the presence of symptomatic cerebrovascular disease; or

(iii) the presence of symptomatic peripheral vascular disease.

The date of the consultation with a specialist physician must be no more than 6 months prior to the application date. The full name of the specialist physician consulted and the date of consultation are to be provided at the time of application.

The qualifying LDL cholesterol level must be provided at the time of application and must have been no more than 2 months old at the time non-PBS subsidised treatment with this drug for this condition was initiated.

If the patient has developed a clinically important product-related adverse event, the clinician must confirm at the time of the application that the maximum tolerated dose of atorvastatin or rosuvastatin has been trialled and has resulted in the patient developing a clinically important product-related adverse event resulting in treatment withdrawal.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin). This retreatment should occur after a washout period of at least 1 month, or if the creatine kinase (CK) level is elevated retreatment should not occur until CK has returned to normal.

In the event of a trial of an alternative statin, the dose of the alternative statin should be increased not more often than every 4 weeks until the maximum tolerated dose has been reached or target LDL-c has been achieved.

With the exception of the situation where the patient is contraindicated to treatment with a statin, the doses and duration of treatment and adverse events experienced with trials with each of atorvastatin and rosuvastatin must be provided at the time of application.

Contraindication to treatment with a statin is as defined in the TGA-approved Product Information.

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

- A completed authority prescription form; and
- A completed Familial heterozygous hypercholesterolaemia Grandfather PBS Authority Application - Supporting Information Form; and
- The date of consultation and the full name of the specialist physician; and
- A copy of the qualifying Dutch Lipid Clinic Network Score or a copy of the result of genetic testing; and
- The result of LDL cholesterol level and one of the following where appropriate: statin treatment details including agent, dose and treatment duration; or details of adverse events to each of atorvastatin and rosuvastatin or contraindication to treatment with a statin as defined in the TGA-approved Product Information.

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge

11485L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	683.24	40.30	Repatha [AN]

evolocumab 140 mg/mL injection, 1 mL pen device

11484K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*630.75	40.30	Repatha [AN]

■ EZETIMIBE

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.

Authority required (STREAMLINED)

7990

Hypercholesterolaemia

Clinical criteria:

- Patient must have homozygous sitosterolaemia.

ezetimibe 10 mg tablet, 30

11408K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	43.13	40.30	^a EZEMICHOL [RW]	^a Ezetrol [MK]
						^a Pharmacor Ezetimibe 10 [CR]	^a Zient 10mg [AF]

■ EZETIMIBE

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.

Authority required (STREAMLINED)

7996

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR

- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Authority required (STREAMLINED)

7966

Hypercholesterolaemia

Clinical criteria:

- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; OR
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment; OR
- Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

- Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

ezetimibe 10 mg tablet, 30

8757X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	43.13	40.30	^a APO-Ezetimibe [TX]	^a Blooms The Chemist Ezetimibe [IB]
						^a EZEMICHOL [RW]	^a Ezetimibe GH [GQ]
						^a Ezetimibe Sandoz [SZ]	^a Ezetrol [MK]
						^a Pharmacor Ezetimibe 10 [CR]	^a Zient 10mg [AF]

LIPID MODIFYING AGENTS, COMBINATIONS

HMG CoA reductase inhibitors in combination with other lipid modifying agents

■ EZETIMIBE + ATORVASTATIN

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

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.

Authority required (STREAMLINED)

7957

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

ezetimibe 10 mg + atorvastatin 80 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10376D	1	5	..	47.67	40.30	Atozet [MK]

ezetimibe 10 mg + atorvastatin 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10377E	1	5	..	46.31	40.30	Atozet [MK]

ezetimibe 10 mg + atorvastatin 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10393B	1	5	..	45.39	40.30	Atozet [MK]

■ EZETIMIBE + ATORVASTATIN

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 The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Authority required (STREAMLINED)

7958

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR

- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

- (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

ezetimibe 10 mg + atorvastatin 10 mg tablet, 30

10392Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	44.66	40.30	Atozet [MK]

■ EZETIMIBE + SIMVASTATIN

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

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.

Authority required (STREAMLINED)

7957

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

ezetimibe 10 mg + simvastatin 40 mg tablet, 30

8881K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	45.47	40.30	^a APO-Ezetimibe/Simvastatin 10/40 [TX] ^a Pharmacor Ezetimibe Simvastatin 10/40 [CR]	^a EZETIMIBE/SIMVASTATIN SANDOZ [SZ] ^a Vytorin [MK]

^a Zeklen 10/40 mg [AF]**ezetimibe 10 mg + simvastatin 80 mg tablet, 30**

8882L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	46.47	40.30	^a APO-Ezetimibe/Simvastatin 10/80 [TX] ^a Pharmacor Ezetimibe Simvastatin 10/80 [CR] ^a Zeklen 10/80 mg [AF]	^a EZETIMIBE/SIMVASTATIN SANDOZ [SZ] ^a Vytorin [MK]

■ EZETIMIBE + SIMVASTATIN**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 The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Authority required (STREAMLINED)**7958**

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

ezetimibe 10 mg + simvastatin 10 mg tablet, 30

9483D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.25	40.30	^a APO-Ezetimibe/Simvastatin 10/10 [TX] ^a Pharmacor Ezetimibe Simvastatin 10/10 [CR] ^a Zeklen 10/10 mg [AF]	^a EZETIMIBE/SIMVASTATIN SANDOZ [SZ] ^a Vytorin [MK]

ezetimibe 10 mg + simvastatin 20 mg tablet, 30

9484E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.76	40.30	^a APO-Ezetimibe/Simvastatin 10/20 [TX] ^a Pharmacor Ezetimibe Simvastatin 10/20 [CR] ^a Zeklen 10/20 mg [AF]	^a EZETIMIBE/SIMVASTATIN SANDOZ [SZ] ^a Vytorin [MK]

■ ROSUVASTATIN (&) EZETIMIBE

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

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.

Authority required (STREAMLINED)

7957

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

rosuvastatin 10 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack

10208G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	45.62	40.30	^a Ezalo Composite Pack 10mg+10mg [AF]	^a Rosuzet Composite Pack [MK]

rosuvastatin 20 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack

10201X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	46.63	40.30	^a Ezalo Composite Pack 10mg+20mg [AF]	^a Rosuzet Composite Pack [MK]

rosuvastatin 40 mg tablet [30] (&) ezetimibe 10 mg tablet [30 tablets], 1 pack

10207F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	48.12	40.30	^a Ezalo Composite Pack 10mg+40mg [AF]	^a Rosuzet Composite Pack [MK]

▪ ROSUVASTATIN (&) EZETIMIBE

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 The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

Authority required (STREAMLINED)

7958

Hypercholesterolaemia

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose, **AND**
- Patient must have coronary heart disease; OR
- Patient must have cerebrovascular disease; OR
- Patient must have peripheral vascular disease; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR

- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
- Patient must have heterozygous familial hypercholesterolaemia; OR
- Patient must have homozygous familial hypercholesterolaemia; OR
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

A clinically important product-related adverse event is defined as follows:

- Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
- Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
- Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

rosuvastatin 5 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack

10204C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.81	40.30	^a Ezalo Composite Pack 10mg+5mg [AF]	^a Rosuzet Composite Pack [MK]

HMG CoA reductase inhibitors, other combinations

■ AMLODIPINE + ATORVASTATIN

amlodipine 5 mg + atorvastatin 10 mg tablet, 30

9049G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	13.90	15.15	Cadivast 5/10 [AF]

amlodipine 10 mg + atorvastatin 40 mg tablet, 30

9055N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.23	17.48	^a Cadivast 10/40 [AF]
			^B 3.00	19.23	17.48	^a Caduet 10/40 [PF]

amlodipine 5 mg + atorvastatin 80 mg tablet, 30

9052K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.91	18.16	^a Cadivast 5/80 [AF]
			^B 3.00	19.91	18.16	^a Caduet 5/80 [PF]

amlodipine 10 mg + atorvastatin 10 mg tablet, 30

9053L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.59	15.84	^a Cadivast 10/10 [AF]
			^B 3.00	17.59	15.84	^a Caduet 10/10 [PF]

amlodipine 5 mg + atorvastatin 40 mg tablet, 30

9051J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.54	16.79	^a Cadivast 5/40 [AF]
			^B 3.00	18.54	16.79	^a Caduet 5/40 [PF]

amlodipine 5 mg + atorvastatin 20 mg tablet, 30

9050H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.63	15.88	Cadivast 5/20 [AF]

amlodipine 10 mg + atorvastatin 80 mg tablet, 30

9056P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.60	18.85	^a Cadivast 10/80 [AF]
			^B 3.00	20.60	18.85	^a Caduet 10/80 [PF]

amlodipine 10 mg + atorvastatin 20 mg tablet, 30

9054M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.32	16.57	^a Cadivast 10/20 [AF]
			^B 3.00	18.32	16.57	^a Caduet 10/20 [PF]

DERMATOLOGICALS

ANTIFUNGALS FOR DERMATOLOGICAL USE

ANTIFUNGALS FOR TOPICAL USE

Antibiotics

■ NYSTATIN

Authority required (STREAMLINED)

6434

Fungal or yeast infection

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

nystatin 100 000 units/g cream, 15 g

1698J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*20.05	21.30	Mycostatin [FM]

Imidazole and triazole derivatives

■ KETOCONAZOLE

Authority required (STREAMLINED)

6434

Fungal or yeast infection

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

ketoconazole 1% shampoo, 100 mL

9025B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	19.91	21.16	Nizoral 1% [JT]

ketoconazole 2% shampoo, 60 mL

1574W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	20.45	21.70	Nizoral 2% [JT]

ketoconazole 2% cream, 30 g

9024Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	26.02	27.27	Nizoral 2% Cream [JT]

■ MICONAZOLE

Authority required (STREAMLINED)

6434

Fungal or yeast infection

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

miconazole 2% solution, 30 mL

9031H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	22.95	24.20	Daktarin Tincture [JT]

miconazole nitrate 2% cream, 70 g

9028E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	20.66	21.91	Daktarin [JT]

miconazole nitrate 2% cream, 30 g

9027D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	18.98	20.23	Daktarin [JT]

miconazole nitrate 2% powder, 30 g

9029F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	19.71	20.96	Daktarin [JT]

Other antifungals for topical use

■ TERBINAFINE

Authority required (STREAMLINED)

6434

Fungal or yeast infection

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

Authority required (STREAMLINED)**6412**

Fungal or yeast infection

Clinical criteria:

- The condition must be fungal; OR
- The condition must be due to yeast.

Population criteria:

- Patient must be 18 years of age or less.

terbinafine hydrochloride 1% cream, 15 g

9160D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*38.39	39.64	Lamisil [GK]

ANTIFUNGALS FOR SYSTEMIC USE*Antifungals for systemic use***■ GRISEOFULVIN****griseofulvin 125 mg tablet, 100**

1460W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	25.21	26.46	Grisovin [QA]

griseofulvin 500 mg tablet, 28

2982Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	26.02	27.27	Grisovin 500 [QA]

■ TERBINAFINE**Authority required**

Dermatophyte infection

Clinical criteria:

- Patient must have failed to respond to topical treatment.

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

Authority required

Dermatophyte infection

Clinical criteria:

- Patient must have failed to respond to topical treatment, **AND**
- Patient must have failed to respond to griseofulvin.

Population criteria:

- Patient must be 18 years of age or less.

terbinafine 250 mg tablet, 42

2285G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	30.39	31.64	^a APO-Terbinafine [TX] ^a Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV] ^a Terbinafine AN [EA] ^a Terbinafine GH [GQ] ^a Tinasil [AF]	^a GenRx Terbinafine [GX] ^a Tamsil [RW] ^a Terbinafine-DRLA [RZ] ^a Terbinafine Sandoz [SZ]

■ TERBINAFINE**Note** No 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**

Onychomycosis

Clinical criteria:

- The condition must be proximal or extensive (greater than 80% nail involvement), **AND**
- Patient must have failed to respond to topical treatment, **AND**
- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

The date of the pathology report must be provided at the time of application and must not be more than 12 months old

terbinafine 250 mg tablet, 42

2804N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	30.39	31.64	^a APO-Terbinafine [TX]	^a GenRx Terbinafine [GX]

NP

^a Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]
^a Terbinafine AN [EA]
^a Terbinafine GH [GQ]
^a Tinasil [AF]

^a Tamsil [RW]

^a Terbinafine-DRLA [RZ]

^a Terbinafine Sandoz [SZ]

■ ANTIPSORIATICS

ANTIPSORIATICS FOR TOPICAL USE

Tars

■ PREPARED COAL TAR

coal tar prepared 2% foam, 100 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10225E	‡1	2	..	34.66	35.91	Scytera [RZ]

NP

Other antipsoriatics for topical use

■ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

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.

Authority required (STREAMLINED)

7947

Chronic stable plaque type psoriasis vulgaris

Clinical criteria:

- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 60 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10075G	‡1	1	..	63.50	40.30	Daivobet 50/500 gel [LO]

NP

■ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

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.

Restricted benefit

Chronic stable plaque type psoriasis vulgaris

Clinical criteria:

- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11091R	‡1	1	..	83.72	40.30	Enstilar [LO]

NP

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
9494Q	‡1	1	..	37.49	38.74	^a Calcipotriol/Betamethasone Sandoz 50/500 [SZ]	^a Daivobet [LO]

NP

ANTIPSORIATICS FOR SYSTEMIC USE

Retinoids for treatment of psoriasis

■ ACITRETIN

Caution This drug is a potent teratogen - pregnancy should be avoided for at least two years after cessation of therapy.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority required (STREAMLINED)

5789

Severe intractable psoriasis

Authority required (STREAMLINED)

5727

Severe disorders of keratinisation

acitretin 10 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2019G	1	2	..	107.73	40.30	^a Neotigason [TB] ^a ZETIN [RW]	^a Novatin [TX]

acitretin 25 mg capsule, 100

2020H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	207.77	40.30	^a Neotigason [TB]	^a Novatin [TX]
						^a ZETIN [RW]	

■ ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

CHEMOTHERAPEUTICS FOR TOPICAL USE

Sulfonamides

■ SILVER SULFADIAZINE

Restricted benefit

Infection

Treatment Phase: Prevention and treatment

Clinical criteria:

- The condition must be in partial or full skin thickness loss due to burns; OR
- The condition must be in partial or full skin thickness loss due to epidermolysis bullosa.

Restricted benefit

Stasis ulcers

silver sulfadiazine 1% cream, 50 g

9479X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	22.01	23.26	Flamazine [SN]

■ CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

CORTICOSTEROIDS, PLAIN

Corticosteroids, weak (group I)

■ HYDROCORTISONE ACETATE

Restricted benefit

Corticosteroid-responsive dermatoses

hydrocortisone acetate 1% ointment, 50 g

2882Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	13.34	14.59	^a Cortic-DS 1% [FM]
			^B 2.35	15.69	14.59	^a Sigmacort [QA]

hydrocortisone acetate 1% cream, 50 g

2881P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	13.34	14.59	^a Cortic-DS 1% [FM]
			^B 2.35	15.69	14.59	^a Sigmacort [QA]

■ HYDROCORTISONE ACETATE

Restricted benefit

Corticosteroid-responsive dermatoses

hydrocortisone acetate 1% ointment, 50 g

5114E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	13.34	14.59	^a Cortic-DS 1% [FM]
			^B 2.35	15.69	14.59	^a Sigmacort [QA]

hydrocortisone acetate 1% cream, 50 g

5113D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	13.34	14.59	^a Cortic-DS 1% [FM]
			^B 2.35	15.69	14.59	^a Sigmacort [QA]

Corticosteroids, moderately potent (group II)

■ TRIAMCINOLONE

Restricted benefit

Corticosteroid-responsive dermatoses

triamcinolone acetonide 0.02% cream, 100 g

2117K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*18.43	19.68	^a Tricortone [FM]
			^B 3.28	*21.71	19.68	^a Aristocort 0.02% [QA]

triamcinolone acetonide 0.02% ointment, 100 g

2118L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*18.43	19.68	^a Tricortone [FM]
			^B 3.28	*21.71	19.68	^a Aristocort 0.02% [QA]

Corticosteroids, potent (group III)■ **BETAMETHASONE DIPROPIONATE****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.

Restricted benefit

Corticosteroid-responsive dermatoses

betamethasone (as dipropionate) 0.05% cream, 15 g

1115Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	17.32	18.57	^a Eleuphrat [FR]
			^B 2.45	19.77	18.57	^a Diprosone [MK]

betamethasone (as dipropionate) 0.05% ointment, 15 g

1119X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	17.32	18.57	^a Eleuphrat [FR]
			^B 2.45	19.77	18.57	^a Diprosone [MK]

■ **BETAMETHASONE DIPROPIONATE****Note Continuing Therapy Only:**

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Authority required (STREAMLINED)

6232

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 10-20% of the patient's body surface area.

betamethasone (as dipropionate) 0.05% cream, 15 g

10824Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*23.17	24.42	^a Eleuphrat [FR]
			^B 4.90	*28.07	24.42	^a Diprosone [MK]

betamethasone (as dipropionate) 0.05% ointment, 15 g

10795E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*23.17	24.42	^a Eleuphrat [FR]
			^B 4.90	*28.07	24.42	^a Diprosone [MK]

■ **BETAMETHASONE DIPROPIONATE****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.

Authority required (STREAMLINED)

6246

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 20-40% of the patient's body surface area.

betamethasone (as dipropionate) 0.05% cream, 15 g

10800K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*34.83	36.08	^a Eleuphrat [FR]
			^B 9.80	*44.63	36.08	^a Diprosone [MK]

betamethasone (as dipropionate) 0.05% ointment, 15 g

10820L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*34.83	36.08	^a Eleuphrat [FR]
			^B 9.80	*44.63	36.08	^a Diprosone [MK]

■ **BETAMETHASONE DIPROPIONATE****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.

Authority required (STREAMLINED)

6218

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

betamethasone (as dipropionate) 0.05% cream, 15 g

10813D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*46.51	40.30	^a Eleuphrat [FR]
			^B 14.70	*61.21	40.30	^a Diprosone [MK]

betamethasone (as dipropionate) 0.05% ointment, 15 g

10821M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*46.51	40.30	^a Eleuphrat [FR]
			^B 14.70	*61.21	40.30	^a Diprosone [MK]

■ BETAMETHASONE DIPROPIONATE**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.

Authority required (STREAMLINED)**6263**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

betamethasone (as dipropionate) 0.05% cream, 15 g

10801L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*58.19	40.30	^a Eleuphrat [FR]
			^B 19.60	*77.79	40.30	^a Diprosone [MK]

betamethasone (as dipropionate) 0.05% ointment, 15 g

10816G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*58.19	40.30	^a Eleuphrat [FR]
			^B 19.60	*77.79	40.30	^a Diprosone [MK]

■ BETAMETHASONE DIPROPIONATE**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.

Authority required (STREAMLINED)**6231**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover >80% of the patient's body surface area.

betamethasone (as dipropionate) 0.05% cream, 15 g

10802M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*69.89	40.30	^a Eleuphrat [FR]
			^B 24.50	*94.39	40.30	^a Diprosone [MK]

betamethasone (as dipropionate) 0.05% ointment, 15 g

10823P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*69.89	40.30	^a Eleuphrat [FR]
			^B 24.50	*94.39	40.30	^a Diprosone [MK]

■ BETAMETHASONE VALERATE**Restricted benefit**

Corticosteroid-responsive dermatoses

betamethasone (as valerate) 0.02% cream, 100 g

2812B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*26.97	28.22	^a Antroquoril [FR]
						^b Cortival 1/5 [FM]
			^B 5.00	*31.97	28.22	^a Celestone-M [MK]
			^B 5.98	*32.95	28.22	^b Betnovate 1/5 [QA]

■ BETAMETHASONE VALERATE**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.

Restricted benefit

Corticosteroid-responsive dermatoses

betamethasone (as valerate) 0.05% cream, 15 g

2813C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	13.21	14.46	^a Cortival 1/2 [FM]
			^B 2.56	15.77	14.46	^a Betnovate 1/2 [QA]

■ BETAMETHASONE VALERATE**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.

Authority required (STREAMLINED)**6232**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 10-20% of the patient's body surface area.

betamethasone (as valerate) 0.05% cream, 15 g

10799J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*14.95	16.20	^a Cortival 1/2 [FM]
			^B 5.12	*20.07	16.20	^a Betnovate 1/2 [QA]

■ BETAMETHASONE VALERATE**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.

Authority required (STREAMLINED)**6246**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 20-40% of the patient's body surface area.

betamethasone (as valerate) 0.05% cream, 15 g

10794D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*18.39	19.64	^a Cortival 1/2 [FM]
			^B 10.24	*28.63	19.64	^a Betnovate 1/2 [QA]

■ BETAMETHASONE VALERATE**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.

Authority required (STREAMLINED)**6218**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

betamethasone (as valerate) 0.05% cream, 15 g

10808W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*21.85	23.10	^a Cortival 1/2 [FM]
			^B 15.36	*37.21	23.10	^a Betnovate 1/2 [QA]

■ BETAMETHASONE VALERATE**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.

Authority required (STREAMLINED)**6263**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

betamethasone (as valerate) 0.05% cream, 15 g

10807T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*25.31	26.56	^a Cortival 1/2 [FM]
			^B 20.48	*45.79	26.56	^a Betnovate 1/2 [QA]

■ BETAMETHASONE VALERATE

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.

Authority required (STREAMLINED)

6231

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover >80% of the patient's body surface area.

betamethasone (as valerate) 0.05% cream, 15 g

10810Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*28.79	30.04	^a Cortival 1/2 [FM]
			^B 25.60	*54.39	30.04	^a Betnovate 1/2 [QA]

■ METHYLPREDNISOLONE

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.

Restricted benefit

Corticosteroid-responsive dermatoses

methylprednisolone aceponate 0.1% ointment, 15 g

8055Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	18.05	19.30	Advantan [BN]

methylprednisolone aceponate 0.1% cream, 15 g

8054X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	18.05	19.30	Advantan [BN]

methylprednisolone aceponate 0.1% ointment: fatty, 15 g

8128T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	18.05	19.30	Advantan [BN]

■ METHYLPREDNISOLONE

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.

Restricted benefit

Eczema

methylprednisolone aceponate 0.1% lotion, 20 g

8618N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	18.64	19.89	Advantan [BN]

■ METHYLPREDNISOLONE

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.

Authority required (STREAMLINED)

6232

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 10-20% of the patient's body surface area.

methylprednisolone aceponate 0.1% ointment, 15 g

10846W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*24.63	25.88	Advantan [BN]

methylprednisolone aceponate 0.1% lotion, 20 g

10856J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*25.81	27.06	Advantan [BN]

methylprednisolone aceponate 0.1% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10842P	2	5	..	*24.63	25.88	Advantan [BN]

methylprednisolone aceponate 0.1% ointment: fatty, 15 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10848Y	2	5	..	*24.63	25.88	Advantan [BN]

■ METHYLPREDNISOLONE**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.

Authority required (STREAMLINED)**6246**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 20-40% of the patient's body surface area.

methylprednisolone aceponate 0.1% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10836H	4	5	..	*37.75	39.00	Advantan [BN]

methylprednisolone aceponate 0.1% lotion, 20 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10838K	3	5	..	*32.95	34.20	Advantan [BN]

methylprednisolone aceponate 0.1% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10855H	4	5	..	*37.75	39.00	Advantan [BN]

methylprednisolone aceponate 0.1% ointment: fatty, 15 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10840M	4	5	..	*37.75	39.00	Advantan [BN]

■ METHYLPREDNISOLONE**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.

Authority required (STREAMLINED)**6231**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover >80% of the patient's body surface area.

methylprednisolone aceponate 0.1% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10845T	10	5	..	*77.19	40.30	Advantan [BN]

methylprednisolone aceponate 0.1% lotion, 20 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10830B	5	5	..	*47.29	40.30	Advantan [BN]

methylprednisolone aceponate 0.1% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10833E	10	5	..	*77.19	40.30	Advantan [BN]

methylprednisolone aceponate 0.1% ointment: fatty, 15 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10843Q	10	5	..	*77.19	40.30	Advantan [BN]

■ METHYLPREDNISOLONE**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.

Authority required (STREAMLINED)

6218

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

methylprednisolone aceponate 0.1% ointment, 15 g

10853F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*50.89	40.30	Advantan [BN]

methylprednisolone aceponate 0.1% cream, 15 g

10835G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*50.89	40.30	Advantan [BN]

methylprednisolone aceponate 0.1% ointment: fatty, 15 g

10844R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*50.89	40.30	Advantan [BN]

■ METHYLPREDNISOLONE**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.

Authority required (STREAMLINED)**6263**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

methylprednisolone aceponate 0.1% ointment, 15 g

10834F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*64.03	40.30	Advantan [BN]

methylprednisolone aceponate 0.1% cream, 15 g

10851D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*64.03	40.30	Advantan [BN]

methylprednisolone aceponate 0.1% ointment: fatty, 15 g

10839L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*64.03	40.30	Advantan [BN]

■ METHYLPREDNISOLONE**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.

Authority required (STREAMLINED)**6263**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

Authority required (STREAMLINED)**6218**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

methylprednisolone aceponate 0.1% lotion, 20 g

10852E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*40.11	40.30	Advantan [BN]

■ MOMETASONE**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.

Restricted benefit

Corticosteroid-responsive dermatoses

mometasone furoate 0.1% ointment, 15 g

1915T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.79	16.04	^a Momasone [QA]	^a Novasone [AF]
						^a Zatamil [EO]	
			^B 3.53	18.32	16.04	^a Elocon [MK]	

mometasone furoate 0.1% lotion, 30 mL

8043H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.71	17.96	^a Momasone [QA]	^a Novasone [AF]
						^a Zatamil [EO]	
			^B 3.53	20.24	17.96	^a Elocon [MK]	

mometasone furoate 0.1% cream, 15 g

1913Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.79	16.04	^a Momasone [QA]	^a Novasone [AF]
						^a Elocon Alcohol Free [MK]	
			^B 3.53	18.32	16.04		

■ MOMETASONE**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.

Authority required (STREAMLINED)**6232**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 10-20% of the patient's body surface area.

mometasone furoate 0.1% ointment, 15 g

10812C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.11	19.36	^a Momasone [QA]	^a Novasone [AF]
						^a Zatamil [EO]	
			^B 7.06	*25.17	19.36	^a Elocon [MK]	

mometasone furoate 0.1% lotion, 30 mL

10819K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.95	23.20	^a Momasone [QA]	^a Novasone [AF]
						^a Zatamil [EO]	
			^B 7.06	*29.01	23.20	^a Elocon [MK]	

mometasone furoate 0.1% cream, 15 g

10827W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.11	19.36	^a Momasone [QA]	^a Novasone [AF]
						^a Elocon Alcohol Free [MK]	
			^B 7.06	*25.17	19.36		

■ MOMETASONE**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.

Authority required (STREAMLINED)**6246**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 20-40% of the patient's body surface area.

mometasone furoate 0.1% ointment, 15 g

10814E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*24.71	25.96	^a Momasone [QA]	^a Novasone [AF]
						^a Zatamil [EO]	
			^B 14.12	*38.83	25.96	^a Elocon [MK]	

mometasone furoate 0.1% lotion, 30 mL

10826T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	5	..	*27.16	28.41	^a Momasone [QA]	^a Novasone [AF]
						^a Zatamil [EO]	
			^B 10.59	*37.75	28.41	^a Elocon [MK]	

mometasone furoate 0.1% cream, 15 g

10809X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*24.71	25.96	^a Momasone [QA]	^a Novasone [AF]

^B14.12 *38.83 25.96 ^a Elocon Alcohol Free [MK]

NP MOMETASONE

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.

Authority required (STREAMLINED)

6218

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

mometasone furoate 0.1% ointment, 15 g

10828X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	..	*31.33	32.58	^a Momasone [QA] ^a Zatamil [EO]	^a Novasone [AF]
			^B 21.18	*52.51	32.58	^a Elocon [MK]	

mometasone furoate 0.1% cream, 15 g

10815F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	5	..	*31.33	32.58	^a Momasone [QA] ^a Elocon Alcohol Free [MK]	^a Novasone [AF]
			^B 21.18	*52.51	32.58	^a Elocon Alcohol Free [MK]	

NP MOMETASONE

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.

Authority required (STREAMLINED)

6263

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

mometasone furoate 0.1% ointment, 15 g

10793C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	8	5	..	*37.95	39.20	^a Momasone [QA] ^a Zatamil [EO]	^a Novasone [AF]
			^B 28.24	*66.19	39.20	^a Elocon [MK]	

mometasone furoate 0.1% cream, 15 g

10818J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	8	5	..	*37.95	39.20	^a Momasone [QA] ^a Elocon Alcohol Free [MK]	^a Novasone [AF]
			^B 28.24	*66.19	39.20	^a Elocon Alcohol Free [MK]	

NP MOMETASONE

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.

Authority required (STREAMLINED)

6231

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover >80% of the patient's body surface area.

mometasone furoate 0.1% ointment, 15 g

10791Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	10	5	..	*44.59	40.30	^a Momasone [QA] ^a Zatamil [EO]	^a Novasone [AF]
			^B 35.30	*79.89	40.30	^a Elocon [MK]	

mometasone furoate 0.1% lotion, 30 mL

10804P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	5	..	*37.64	38.89	^a Momasone [QA] ^a Zatamil [EO]	^a Novasone [AF]
			^B 17.65	*55.29	38.89	^a Elocon [MK]	

mometasone furoate 0.1% cream, 15 g

10792B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	10	5	..	*44.59	40.30	^a Momasone [QA]	^a Novasone [AF]
			^B 35.30	*79.89	40.30	^a Elocon Alcohol Free [MK]	

■ MOMETASONE**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.

Authority required (STREAMLINED)**6263**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 60-80% of the patient's body surface area.

Authority required (STREAMLINED)**6218**

Corticosteroid-responsive dermatoses

Clinical criteria:

- The condition must cover 40-60% of the patient's body surface area.

mometasone furoate 0.1% lotion, 30 mL

10805Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*32.39	33.64	^a Momasone [QA]	^a Novasone [AF]
			^B 14.12	*46.51	33.64	^a Zatamil [EO]	
						^a Elocon [MK]	

*Corticosteroids, very potent (group IV)***■ CLOBETASOL****Authority required (STREAMLINED)****5461**

Moderate to severe scalp psoriasis

Clinical criteria:

- The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR
- The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.

Population criteria:

- Patient must be aged 18 years or older.

clobetasol propionate 0.05% shampoo, 125 mL

10080M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	47.32	40.30	Clobex [GA]

■ ANTI-ACNE PREPARATIONS**ANTI-ACNE PREPARATIONS FOR TOPICAL USE***Retinoids for topical use in acne***■ ADAPALENE + BENZOYL PEROXIDE****Restricted benefit**

Severe acne vulgaris

Treatment Phase: Acute treatment

Clinical criteria:

- The treatment must in combination with an oral antibiotic.

adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

8954G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	36.68	37.93	Epiduo [GA]

■ ADAPALENE + BENZOYL PEROXIDE**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.

Restricted benefit

Severe acne vulgaris

Clinical criteria:

- The treatment must be maintenance therapy.

DERMATOLOGICALS

adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

8955H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	3	..	36.68	37.93	Epiduo [GA]

ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE

Retinoids for treatment of acne

ISOTRETINOIN

Caution This drug causes birth defects.

This drug has been reported to cause other frequent and potentially serious toxicity.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority required (STREAMLINED)

5224

Severe cystic acne

Clinical criteria:

- The condition must be unresponsive to other therapy.

isotretinoin 10 mg capsule, 60

2591J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	35.16	36.41	^a APO-Isotretinoin [TX] ^a Isotretinoin AN [EA] ^a Rocta 10 [RW]	^a Dermatane [ER] ^a Oratane [RF]

isotretinoin 5 mg capsule, 60

11716P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	23.32	24.57	Oratane [OU]

isotretinoin 40 mg capsule, 30

2549E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	44.79	40.30	^a Dermatane [ER]	^a Oratane [RF]

ISOTRETINOIN

Caution This drug causes birth defects.

This drug has been reported to cause other frequent and potentially serious toxicity.

Note Pharmaceutical benefits that have form pack size isotretinoin 20 mg capsule, 60 and isotretinoin 20 mg capsule, 30 are equivalent for the purposes of substitution.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority required (STREAMLINED)

5224

Severe cystic acne

Clinical criteria:

- The condition must be unresponsive to other therapy.

isotretinoin 20 mg capsule, 30

11621P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*48.39	40.30	^a Roaccutane [RO]

isotretinoin 20 mg capsule, 60

2592K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	48.38	40.30	^a APO-Isotretinoin [TX] ^a Isotretinoin AN [EA] ^a Oratane [RF] ^a Rocta 20 [RW]	^a Dermatane [ER] ^a Isotretinoin SCP 20 [CR] ^a Roaccutane [RO]

OTHER DERMATOLOGICAL PREPARATIONS

OTHER DERMATOLOGICAL PREPARATIONS

Agents for dermatitis, excluding corticosteroids

PIMECROLIMUS

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

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

Authority required (STREAMLINED)

5482

Atopic dermatitis

Population criteria:

- Patient must be at least 3 months of age.

Clinical criteria:

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid, **AND**
- Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

Authority required (STREAMLINED)**5472**

Atopic dermatitis

Treatment Phase: Short-term (up to 3 weeks) intermittent treatment

Population criteria:

- Patient must be at least 3 months of age.

Clinical criteria:

- The condition must be on the patient's face; OR
 - The condition must be on the patient's eyelid, **AND**
 - Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy, **AND**
 - The condition must have been initially diagnosed more than three months prior to this treatment, **AND**
 - Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.
- Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:
- (i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or
 - (ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or
 - (iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or
 - (iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

pimecrolimus 1% cream, 15 g

8802G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	31.83	33.08	Elidel [GO]

*Other dermatologicals***■ DAPSONE****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.

dapsone 100 mg tablet, 100

1272Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	318.59	40.30	Link Medical Products Pty Ltd [LM]

dapsone 25 mg tablet, 100

8801F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	260.58	40.30	Link Medical Products Pty Ltd [LM]

■ IMIQUIMOD

Note The patient or carer must be able to understand and administer the imiquimod dosing regimen.

Note No 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 Treatment of recurrent (previously treated) lesions will not be authorised.

Note Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

Authority required

Superficial basal cell carcinoma

Clinical criteria:

- The condition must be previously untreated, **AND**
 - The condition must be confirmed by biopsy, **AND**
 - Patient must have normal immune function, **AND**
 - The condition must not be suitable for treatment with surgical excision; OR
 - The condition must not be suitable for treatment with cryotherapy; OR
 - The condition must not be suitable for treatment with curettage with diathermy, **AND**
 - Patient must require topical drug therapy.
- The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

imiquimod 5% cream, 12 x 250 mg sachets

2546B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	87.01	40.30	^a Aldiq [QA]	^a APO-Imiquimod [TX]
			^B 2.28	89.29	40.30	^a Aldara [IL]	

imiquimod 5% cream, 2 x 2 g

2637T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	^B 4.55	91.56	40.30	^a Aldara Pump [IL]

GENITO URINARY SYSTEM AND SEX HORMONES
OTHER GYNECOLOGICALS
CONTRACEPTIVES FOR TOPICAL USE
Intrauterine contraceptives
LEVONORGESTREL
Restricted benefit

Contraception

Restricted benefit

Idiopathic menorrhagia

Clinical criteria:

- The treatment must be in a patient where oral treatments are ineffective.

Restricted benefit

Idiopathic menorrhagia

Clinical criteria:

- The treatment must be in a patient where oral treatments are contraindicated.

levonorgestrel 52 mg intrauterine drug delivery system, 1 system

8633J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	208.46	40.30	Mirena [BN]

NP

OTHER GYNECOLOGICALS
Prolactine inhibitors
BROMOCRIPTINE
Restricted benefit

Prevention of the onset of lactation

Clinical criteria:

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

bromocriptine 2.5 mg tablet, 30

1444B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	22.35	23.60	Parlodel [SZ]

NP

BROMOCRIPTINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Restricted benefit

Acromegaly

Restricted benefit

Parkinson disease

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had radiotherapy for this condition with incomplete resolution.

bromocriptine 2.5 mg tablet, 30

1443Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*33.23	34.48	Parlodel [SZ]

■ CABERGOLINE**Restricted benefit**

Prevention of the onset of lactation

Clinical criteria:

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

cabergoline 500 microgram tablet, 2

8115D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	24.84	26.09	^a APO-Cabergoline [TX]	^a Dostinex [PF]

NP

■ CABERGOLINE**Restricted benefit**

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had radiotherapy for this condition with incomplete resolution.

cabergoline 500 microgram tablet, 8

8114C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	64.94	40.30	^a APO-Cabergoline [TX]	^a Dostinex [PF]

■ QUINAGOLIDE**Restricted benefit**

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had radiotherapy for this condition with incomplete resolution.

quinagolide 25 microgram tablet [3] (&) quinagolide 50 microgram tablet [3], 6

8860H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	15.23	16.48	Norprolac [FP]

quinagolide 75 microgram tablet, 30

8822H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	48.98	40.30	Norprolac [FP]

SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE

Progestogens and estrogens, fixed combinations

LEVONORGESTREL + ETHINYLESTRADIOL

levonorgestrel 150 microgram + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

1394J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	17.59	18.84	^a Monofeme 28 [FZ] ^b Eleanor 150/30 ED [EA] ^b Femme-Tab ED 30/150 [AE] ^b Micronelle 30 ED [TX]	^b Evelyn 150/30 ED [GQ] ^b Lenest 30 ED [AF]
			^B 3.50	21.09	18.84	^b Levlen ED [SY]	
			^B 11.56	29.15	18.84	^a Nordette 28 [PF]	

levonorgestrel 100 microgram + ethinylestradiol 20 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

2416E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.59	18.84	Femme-Tab ED 20/100 [AE]

levonorgestrel 125 microgram + ethinylestradiol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

1456P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.20	20.45	Microgynon 50 ED [BN]

NORETHISTERONE + ETHINYLESTRADIOL

norethisterone 500 microgram + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

2774B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	20.21	21.46	^a Norimin 28 Day [FZ] ^B 9.78 29.99 21.46 ^a Brevinor [PF]

norethisterone 1 mg + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

2775C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	20.21	21.46	^a Norimin-1 28 Day [FZ] ^B 9.78 29.99 21.46 ^a Brevinor-1 [PF]

NORETHISTERONE + MESTRANOL

norethisterone 1 mg + mestranol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28

3179H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	21.11	22.36	Norinyl-1/28 [PF]

Progestogens and estrogens, sequential preparations

LEVONORGESTREL + ETHINYLESTRADIOL

ethinylestradiol 30 microgram + levonorgestrel 50 microgram tablet [24] (&) ethinylestradiol 40 microgram + levonorgestrel 75 microgram tablet [20] (&) ethinylestradiol 30 microgram + levonorgestrel 125 microgram tablet [40] (&) inert substance tablet [28], 112 [4 x 28]

1392G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.20	20.45	^a Trifeme 28 [FZ] ^b Logynon ED [SY]
			^B 13.00	32.20	20.45	^a Triphasil 28 [PF]
			^B 13.56	32.76	20.45	^b Triquilar ED [BN]

Progestogens

ETONOGESTREL

etonogestrel 68 mg implant, 1

8487Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	..	..	167.03	40.30	Implanon NXT [MK]

LEVONORGESTREL

levonorgestrel 30 microgram tablet, 112 tablets [4 x 28]

2913H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	2	..	19.18	20.43	Microlut 28 [BN]

MEDROXYPROGESTERONE

medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial

3118D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	25.61	26.86	^a Depo-Ralovera [FZ]

^B7.00 32.61 26.86 ^a Depo-Provera [PF]

NP NORETHISTERONE

norethisterone 350 microgram tablet, 4 x 28

1967M

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	2	..	20.21	21.46	Noriday 28 Day [PF]

NP

General

ANDROGENS

3-oxoandrosten (4) derivatives

TESTOSTERONE

Authority required

Androgen deficiency

Clinical criteria:

- Patient must have an established pituitary or testicular disorder.

Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

- Patient must be aged 40 years or older.

Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

testosterone 2% (23 mg/actuation) gel, 56 actuations

11740X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	82.43	40.30	Testavan [FP]

testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations

10380H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	4	..	76.98	40.30	Testogel [HB]

testosterone 5% (50 mg/mL) cream, 50 mL

10378F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	6	..	65.22	40.30	AndroForte 5 [LX]

testosterone 2.5 mg/24 hours patch, 60

8460G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	77.51	40.30	Androderm [TB]

testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets

8830R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	76.98	40.30	Testogel [HB]

testosterone 5 mg/24 hours patch, 30

8619P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	77.51	40.30	Androderm [TB]

■ TESTOSTERONE UNDECANOATE
Authority required

Androgen deficiency

Clinical criteria:

- Patient must have an established pituitary or testicular disorder.

Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

- Patient must be aged 40 years or older.

Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

testosterone undecanoate 1 g/4 mL modified release injection, 4 mL vial

10205D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	115.59	40.30	Reandron 1000 [BN]

testosterone undecanoate 40 mg capsule, 60

2115H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	33.45	34.70	Andriol Testocaps [MK]

ESTROGENS

Natural and semisynthetic estrogens, plain

■ **ESTRADIOL**

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.

estradiol valerate 2 mg tablet, 56

1664N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.98	19.23	Progynova [BN]

estradiol valerate 1 mg tablet, 56

1663M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	16.05	17.30	Progynova [BN]

estradiol 10 microgram modified release pessary, 18

10203B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	33.55	34.80	Vagifem Low [NO]

estradiol 2 mg tablet, 56

8274L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.68	18.93	Zumenon [GO]

■ **ESTRADIOL**

Note Estradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

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.

estradiol 100 microgram/24 hours patch, 8

8312L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	22.53	23.78	Estraderm MX 100 [JU]

estradiol 100 microgram/24 hours patch, 8

8765H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	22.53	23.78	Estradot 100 [SZ]

estradiol 50 microgram/24 hours patch, 4

8125P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	20.76	22.01	Climara 50 [BN]

estradiol 25 microgram/24 hours patch, 8

8311K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.76	22.01	Estraderm MX 25 [JU]

estradiol 25 microgram/24 hours patch, 8

8761D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.76	22.01	Estradot 25 [SZ]

estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets

8286D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.76	22.01	Sandrena [AS]

estradiol 37.5 microgram/24 hours patch, 8

8762E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.76	22.01	Estradot 37.5 [SZ]

estradiol 25 microgram/24 hours patch, 4

8485N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.76	22.01	Climara 25 [BN]

estradiol 50 microgram/24 hours patch, 8

8140K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.76	22.01	Estraderm MX 50 [JU]

estradiol 50 microgram/24 hours patch, 8

8763F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	20.76	22.01	Estradot 50 [SZ]

estradiol 75 microgram/24 hours patch, 8

8764G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	22.53	23.78	Estradot 75 [SZ]

estradiol 75 microgram/24 hours patch, 4

8486P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	22.53	23.78	Climara 75 [BN]

estradiol 100 microgram/24 hours patch, 4

8126Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	22.53	23.78	Climara 100 [BN]

■ ESTRADIOL**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.

estriol 500 microgram pessary, 15

1771F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	24.29	25.54	Ovestin Ovula [AS]

estriol 0.1% (1 mg/g) cream, 15 g

1781R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	22.80	24.05	Ovestin [AS]

PROGESTOGENS*Pregnen (4) derivatives***■ MEDROXYPROGESTERONE****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.

medroxyprogesterone acetate 5 mg tablet, 56

2323G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.48	20.73	^a Ralovera [FZ]
			^b 6.70	26.18	20.73	^a Provera [PF]

medroxyprogesterone acetate 10 mg tablet, 30

2321E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	18.35	19.60	^a Ralovera [FZ]
			^B 6.70	25.05	19.60	^a Provera [PF]

■ MEDROXYPROGESTERONE**Restricted benefit**

Endometriosis

medroxyprogesterone acetate 10 mg tablet, 100

2722G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	34.38	35.63	^a Ralovera [FZ]
			^B 6.70	41.08	35.63	^a Provera [PF]

*Estren derivatives***■ NORETHISTERONE****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.

norethisterone 5 mg tablet, 30

2993M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	33.69	34.94	Primolut N [BN]

PROGESTOGENS AND ESTROGENS IN COMBINATION*Progestogens and estrogens, fixed combinations***■ ESTRADIOL + DYDROGESTERONE****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.

estradiol 1 mg + dydrogesterone 5 mg tablet, 28

10142T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	22.21	23.46	Femoston-Conti [GO]

■ ESTRADIOL + NORETHISTERONE ACETATE**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.

estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8

8427M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	22.53	23.78	Estalis continuous 50/140 [SZ]

estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8

8428N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	22.53	23.78	Estalis continuous 50/250 [SZ]

*Progestogens and estrogens, sequential preparations***■ ESTRADIOL (&) ESTRADIOL + DYDROGESTERONE****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.

estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28

10146B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	22.21	23.46	Femoston 1/10 [GO]

estradiol 2 mg tablet [14] (&) estradiol 2 mg + dydrogesterone 10 mg tablet [14], 28

8244X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	22.21	23.46	Femoston 2/10 [GO]

■ NORETHISTERONE ACETATE + ESTRADIOL (&) ESTRADIOL

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.

estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 8

8425K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	22.53	23.78	Estalis sequi 50/140 [SZ]

estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 8

8426L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	22.53	23.78	Estalis sequi 50/250 [SZ]

GONADOTROPINS AND OTHER OVULATION STIMULANTS

Gonadotropins

■ FOLLITROPIN ALFA

Note Biosimilar prescribing policy Prescribing of the biosimilar brand, Bemfola, is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

Note Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Restricted benefit

Anovulatory infertility

Note Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Note Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Restricted benefit

Infertility

Clinical criteria:

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL pen devices

10877L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*916.24	40.30	Bemfola [FX]

follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL pen devices

10865W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*460.72	40.30	Bemfola [FX]

follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL pen device

8714P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*551.83	40.30	Gonal-f Pen [SG]

follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL pen device

8713N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*369.61	40.30	Gonal-f Pen [SG]

follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL pen device

8715Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*734.05	40.30	Gonal-f Pen [SG]

follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL pen devices

10876K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*1348.60	40.30	Bemfola [FX]

■ FOLLITROPIN BETA

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

Note Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Restricted benefit

Anovulatory infertility

Note Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Note Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Restricted benefit

Infertility

Clinical criteria:

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

8566W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*534.35	40.30	Puregon 600 IU/0.72 mL [MK]

follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge

8871X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*791.85	40.30	Puregon 900 IU/1.08 mL [MK]

follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge

8565T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*411.94	40.30	Puregon 300 IU/0.36 mL [MK]

■ **HUMAN CHORIONIC GONADOTROPHIN**

Note Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Restricted benefit

Anovulatory infertility

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

Note Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Note Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Restricted benefit

Infertility

Population criteria:

- Patient must be male.

Clinical criteria:

- The condition must be due to hypogonadotrophic hypogonadism.

Restricted benefit

Infertility

Population criteria:

- Patient must be male.

Clinical criteria:

- The condition must be associated with isolated luteinising hormone deficiency.

Restricted benefit

Combined deficiency of human growth hormone and gonadotrophins

Population criteria:

- Patient must be male.

Clinical criteria:

- Patient must be one in whom the absence of secondary sexual characteristics indicates a lag in maturation.

Restricted benefit

Hypogonadism or delayed puberty

Population criteria:

- Patient must be male, **AND**
- Patient must be aged 16 years or older.

Clinical criteria:

- Patient must show clinical evidence of the condition, **AND**
- The treatment must not extend beyond 6 months.

GENITO URINARY SYSTEM AND SEX HORMONES

human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack

11148R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	45.43	40.30	Pregnyl [MK]

Ovulation stimulants, synthetic

■ CLOMIFENE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Restricted benefit

Anovulatory infertility

Restricted benefit

Patients undergoing in-vitro fertilisation

clomifene citrate 50 mg tablet, 10

1211R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	35.91	37.16	Clomid [SW]

ANTIANDROGENS

Antiandrogens, plain

■ CYPROTERONE

cypoterone acetate 50 mg tablet, 50

1270W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*83.09	40.30	^a ANTERONE 50 [RW] ^a Cyprocur 50 [QA] ^a Cyprostat [SY] ^a Cyproterone Sandoz [HX] ^a Pharmacor Cyproterone 50 [CR]	^a APO-Cyproterone [TX] ^a Cyprone 50 [AL] ^a Cyproterone AN [EA] ^a GenRx Cyproterone Acetate [GX]
			^B 2.28	*85.37	40.30	^a Androcur [BN]	

cypoterone acetate 100 mg tablet, 50

8019C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	67.26	40.30	^a ANTERONE 100 [RW] ^a Cyprocur 100 [QA] ^a Cyprostat-100 [SY] ^a Cyproterone Sandoz [HX] ^a Pharmacor Cyproterone 100 [CR]	^a APO-Cyproterone [TX] ^a Cyprone 100 [AF] ^a Cyproterone AN [EA] ^a GenRx Cyproterone Acetate [GX]
			^B 1.41	68.67	40.30	^a Androcur-100 [BN]	

■ CYPROTERONE

Caution This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

Authority required (STREAMLINED)

5532

Moderate to severe androgenisation

Clinical criteria:

- The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

Population criteria:

- Patient must be female.

Clinical criteria:

- Patient must not be pregnant.

cypoterone acetate 50 mg tablet, 20

1269T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	25.80	27.05	^a ANTERONE 50 [RW] ^a Cyprocur 50 [QA] ^a Cyprostat [SY] ^a Cyproterone Sandoz [HX] ^a Pharmacor Cyproterone 50 [CR]	^a APO-Cyproterone [TX] ^a Cyprone 50 [AL] ^a Cyproterone AN [EA] ^a GenRx Cyproterone Acetate [GX]
			^B 2.40	28.20	27.05	^a Androcur [BN]	

OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

Antigonadotropins and similar agents

■ DANAZOL

Caution Pregnancy must be excluded prior to administration of this drug.

Authority required (STREAMLINED)

6293

Endometriosis

Clinical criteria:

- The condition must be visually proven.

Authority required (STREAMLINED)

6285

Hereditary angio-oedema

Authority required (STREAMLINED)

6259

Intractable primary menorrhagia

Clinical criteria:

- The treatment must be for the short-term (up to 6 months).

Note Treatment of this indication is limited to 6 months. See Australian Product Information

Authority required (STREAMLINED)

6242

Breast disease

Clinical criteria:

- The treatment must be for the short-term (up to 6 months), **AND**
- The condition must be severe benign (fibrocystic) breast disease; OR
- The condition must be mastalgia associated with severe symptomatic benign breast disease, **AND**
- The condition must be refractory to treatment with other drugs.

Note Treatment of this indication is limited to 6 months. See Australian Product Information

danazol 200 mg capsule, 100

1287R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	70.96	40.30	Azol 200 [AF]

danazol 100 mg capsule, 100

1285P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	49.99	40.30	Azol 100 [AF]

Progesterone receptor modulators

■ MIFEPRISTONE (&) MISOPROSTOL

Note No 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

Termination of an intra-uterine pregnancy

Clinical criteria:

- The condition must be an intra-uterine pregnancy of up to 63 days of gestation.

Treatment criteria:

- Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.

mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack

10211K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	312.18	40.30	MS-2 Step [XH]

■ UROLOGICALS

UROLOGICALS

Drugs for urinary frequency and incontinence

■ OXYBUTYNIN

Restricted benefit

Detrusor overactivity

oxybutynin hydrochloride 5 mg tablet, 100

8039D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	15.29	16.54	^a Ditropan [SW]	^a Oxybutynin Sandoz [SZ]

■ OXYBUTYNIN

Restricted benefit

Detrusor overactivity

Clinical criteria:

- Patient must be unable to tolerate oral oxybutynin; OR

- Patient must be unable to swallow oral oxybutynin.

oxybutynin 3.9 mg/24 hours patch, 8

9454N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	36.53	37.78	Oxytrol [TT]

■ PROPANTHELINE

Restricted benefit

Detrusor overactivity

propantheline bromide 15 mg tablet, 100

1953T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*25.63	26.88	Pro-Banthine [RW]

Other urologicals

■ BICARBONATE

sodium bicarbonate 840 mg capsule, 100

9470K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.67	20.92	Sodibic [AS]

■ PHENOXYBENZAMINE

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.

Restricted benefit

Phaeochromocytoma

Restricted benefit

Neurogenic urinary retention

phenoxybenzamine hydrochloride 10 mg capsule, 100

1862B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	948.46	40.30	Dibenyline [GH]

phenoxybenzamine hydrochloride 10 mg capsule, 100

9286R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	948.46	40.30	Dibenzyl [BZ]

phenoxybenzamine hydrochloride 10 mg capsule, 30

1166J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*854.11	40.30	Amdipharm Mercury (Australia) Pty Limited [GH]

DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

Alpha-adrenoreceptor antagonists

■ DUTASTERIDE + TAMSULOSIN

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.

Authority required (STREAMLINED)

6189

Benign prostatic hyperplasia

Clinical criteria:

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia.

dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30

5490Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	32.36	33.61	Duodart 500ug/400ug [GK]

Testosterone-5-alpha reductase inhibitors

■ DUTASTERIDE

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.

Authority required (STREAMLINED)**6202**

Benign prostatic hyperplasia

Clinical criteria:

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia, **AND**
- The treatment must be in combination with an alpha-antagonist.

dutasteride 500 microgram capsule, 30

5468T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	28.15	29.40	^a APO-Dutasteride [TX]
			^B 7.00	35.15	29.40	^a Avodart [GK]

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

ACTH

■ TETRACOSACTIDE (TETRACOSACTRIN)

Restricted benefit

Hypsarrhythmia and/or infantile spasms

tetracosactide (tetracosactrin) 1 mg/mL modified release injection, 1 mL ampoule

2832C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*385.74	40.30	Synacthen Depot 1 mg/1 mL [LM]

Thyrotropin

■ THYROTROPIN ALFA

Restricted benefit

Ablation of thyroid remnant tissue

Clinical criteria:

- Patient must have undergone a thyroidectomy, **AND**
- The treatment must be in combination with radioactive iodine, **AND**
- Patient must not have a known metastatic disease.

thyrotropin alfa 900 microgram injection, 2 vials

2700D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1630.67	40.30	Thyrogen [GZ]

POSTERIOR PITUITARY LOBE HORMONES

Vasopressin and analogues

■ DESMOPRESSIN

Authority required (STREAMLINED)**5266**

Cranial diabetes insipidus

desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL

2129C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*125.79	40.30	Minirin [FP]

desmopressin acetate 200 microgram tablet, 30

8662X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*139.57	40.30	Minirin [FP]

desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations

8711L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*125.65	40.30	Minirin Nasal Spray [FP]

■ DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.**Note** Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.**Authority required (STREAMLINED)****5413**

Primary nocturnal enuresis

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be refractory to an enuresis alarm.

Authority required (STREAMLINED)**5295**

Primary nocturnal enuresis

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin acetate 200 microgram tablet, 30

8663Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	54.18	40.30	Minirin [FP]

■ DESMOPRESSIN

Caution Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

Note Not to be used in preference to enuresis alarms.

Authority required (STREAMLINED)**5342**

Primary nocturnal enuresis

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be refractory to an enuresis alarm.

Authority required (STREAMLINED)**5267**

Primary nocturnal enuresis

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations

8712M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	68.56	40.30	Minirin Nasal Spray [FP]

■ DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Note Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

Authority required (STREAMLINED)**5412**

Primary nocturnal enuresis

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be refractory to an enuresis alarm.

Authority required (STREAMLINED)**5226**

Primary nocturnal enuresis

Population criteria:

- Patient must be 6 years of age or older.

Clinical criteria:

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin 240 microgram sublingual wafer, 30

8975J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	92.35	40.30	Minirin Melt [FP]

desmopressin 120 microgram sublingual wafer, 30

9398P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.06	40.30	Minirin Melt [FP]

HYPOTHALAMIC HORMONES*Gonadotropin-releasing hormones***■ NAFARELIN****Restricted benefit**

Endometriosis

Treatment Phase: Initial treatment, for up to 6 months

Clinical criteria:

- The condition must be visually proven.

Restricted benefit

Endometriosis

Treatment Phase: Subsequent treatment, for up to 6 months

Clinical criteria:

- The condition must be visually proven, **AND**
- The treatment must not be within 2 years of the end of the previous course of treatment with this drug, **AND**
- Patient must have had a recent bone density assessment.

The date of the bone density assessment must be recorded in the patient's medical records.

nafarelin 200 microgram/actuation nasal spray, 60 actuations

2962X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	121.80	40.30	Synarel [PF]

■ CORTICOSTEROIDS FOR SYSTEMIC USE**CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN***Mineralocorticoids***■ FLUDROCORTISONE ACETATE****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.

fludrocortisone acetate 100 microgram tablet, 100

1433K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*40.39	40.30	Florinef [QA]

*Glucocorticoids***■ BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE****Restricted benefit**

Local intra-articular or peri-articular infiltration

Restricted benefit

Keloid

Restricted benefit

Lichen planus hypertrophic

betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules

5034Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	27.64	28.89	Celestone Chronodose [MK]

■ BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**Note Shared Care Model:**

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

Restricted benefit

Alopecia areata

Restricted benefit

Local intra-articular or peri-articular infiltration

Restricted benefit

Granulomata

Clinical criteria:

- The condition must be dermal.

Restricted benefit

Keloid

Restricted benefit

Lichen planus hypertrophic

Restricted benefit

Lichen simplex chronicus

Restricted benefit

Chronic discoid lupus erythematosus

Restricted benefit

Necrobiosis lipoidica

Restricted benefit

Uveitis

betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules

2694T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	27.64	28.89	Celestone Chronodose [MK]

■ CORTISONE**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.

cortisone acetate 25 mg tablet, 60

1247P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	23.94	25.19	Cortate [AS]

cortisone acetate 5 mg tablet, 50

1246N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	18.81	20.06	Cortate [AS]

■ DEXAMETHASONE**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.

dexamethasone 500 microgram tablet, 30

1292B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	13.58	14.83	Dexamethasone [AS]

dexamethasone 4 mg tablet, 30

2507Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	16.68	17.93	Dexamethasone [AS]

■ DEXAMETHASONE PHOSPHATE**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.

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

2509C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.60	18.85	^a Dexamethasone Mylan [AF]	^a Hospira Pty Limited [PF]

dexamethasone phosphate 8 mg/2 mL injection, 5 x 2 mL vials

1291Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	26.49	27.74	^a Dexamethasone Mylan [AF]	^a Hospira Pty Limited [PF]

■ HYDROCORTISONE**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.

hydrocortisone 20 mg tablet, 60

1500Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
(NP)	1	4	..	32.12	33.37	^a Hydrocortisone Mylan 20 [AL]	^a Hysone 20 [AF]

hydrocortisone 4 mg tablet, 50

1499X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
(NP)	1	4	..	25.94	27.19	^a Hydrocortisone Mylan 4 [AL]	^a Hysone 4 [AF]

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

1501B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	2	..	..	*21.29	22.54	Solu-Cortef [PF]

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

3096Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	1	..	..	20.24	21.49	Solu-Cortef [PF]

■ HYDROCORTISONE SODIUM SUCCINATE**Restricted benefit**

For use in a hospital

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

1510L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	6	..	..	*40.87	40.30	Solu-Cortef [PF]

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

5118J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(DP)	6	..	..	*40.87	40.30	Solu-Cortef [PF]

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

1511M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	6	..	..	*64.03	40.30	Solu-Cortef [PF]

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

5119K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(DP)	6	..	..	*64.03	40.30	Solu-Cortef [PF]

■ METHYLPREDNISOLONE**methylprednisolone 1 g injection, 1 vial**

5264C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
(NP)	1	..	..	43.98	40.30	^a Methylpred [AL]	^a Methylprednisolone Alphapharm [AF]
						^a Solu-Medrol [PF]	

■ METHYLPREDNISOLONE**Restricted benefit**

Local intra-articular or peri-articular infiltration

methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials

1928L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	1	..	..	22.86	24.11	^a Depo-Nisolone [FZ]
			^b 2.61	25.47	24.11	^a Depo-Medrol [PF]

■ METHYLPREDNISOLONE**Restricted benefit**

Local intra-articular or peri-articular infiltration

methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials

5148Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(DP)	1	..	..	22.86	24.11	^a Depo-Nisolone [FZ]
			^b 2.61	25.47	24.11	^a Depo-Medrol [PF]

■ METHYLPREDNISOLONE

Note Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.

methylprednisolone 40 mg injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack

11739W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	..	..	*41.09	40.30	^a Solu-Medrol [PF]

methylprednisolone 40 mg injection, 5 vials

5263B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.62	24.87	^a Methylpred [AL]

■ PREDNISOLONE**prednisolone 25 mg tablet, 30**

1916W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	15.76	17.01	Panafcortelone [AS]	Solone [IL]

prednisolone 1 mg tablet, 100

3152X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	14.04	15.29	^a Predsolone [LN]
			^B 1.00	15.04	15.29	^a Panafcortelone [AS]

prednisolone 5 mg tablet, 60

1917X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	14.48	15.73	Panafcortelone [AS]	Solone [IL]

■ PREDNISOLONE SODIUM PHOSPHATE**prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL**

8285C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	18.68	19.93	^a PredMix [LN]
			^B 2.35	21.03	19.93	^a Redipred [AS]

■ PREDNISONE**prednisone 1 mg tablet, 100**

1934T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	13.99	15.24	^a Predsone [LN]
			^B 1.00	14.99	15.24	^a Panafcort [AS]

prednisone 5 mg tablet, 60

1935W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	14.39	15.64	Panafcort [AS]	Sone [IL]

prednisone 25 mg tablet, 30

1936X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	15.82	17.07	Panafcort [AS]	Sone [IL]

■ TRIAMCINOLONE**Restricted benefit**

Local intra-articular or peri-articular infiltration

Restricted benefit

Keloid

Restricted benefit

Lichen planus hypertrophic

triamcinolone acetate 10 mg/mL injection, 5 x 1 mL ampoules

5233K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	27.64	28.89	Kenacort-A10 [QA]

■ TRIAMCINOLONE**Note Shared Care Model:**

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

Restricted benefit

Alopecia areata

Restricted benefit

Local intra-articular or peri-articular infiltration

Restricted benefit

Granulomata

Clinical criteria:

- The condition must be dermal.

Restricted benefit

Keloid

Restricted benefit

Lichen planus hypertrophic

Restricted benefit

Lichen simplex chronicus

Restricted benefit

Chronic discoid lupus erythematosus

Restricted benefit

Necrobiosis lipoidica

Restricted benefit

Psoriasis

triamcinolone acetate 10 mg/mL injection, 5 x 1 mL ampoules

2990J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	27.64	28.89	Kenacort-A10 [QA]

■ **THYROID THERAPY****THYROID PREPARATIONS***Thyroid hormones*■ **LEVOTHYROXINE****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.

levothyroxine sodium 50 microgram tablet, 200

2174K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	26.22	27.47	^a Eutroxsig [FM]
			^B 1.91	28.13	27.47	^a Oroxine [QA]

levothyroxine sodium 200 microgram tablet, 200

2173J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	29.38	30.63	^a Eutroxsig [FM]
			^B 1.93	31.31	30.63	^a Oroxine [QA]

levothyroxine sodium 75 microgram tablet, 200

9287T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	26.78	28.03	^a Eutroxsig [FM]
			^B 1.98	28.76	28.03	^a Oroxine [QA]

levothyroxine sodium 100 microgram tablet, 200

2175L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	26.75	28.00	^a Eutroxsig [FM]
			^B 1.92	28.67	28.00	^a Oroxine [QA]

■ **LIOTHYRONINE****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.

Authority required (STREAMLINED)**6382**

Thyroid cancer

Authority required (STREAMLINED)**6410**

Hypothyroidism

Clinical criteria:

- The treatment must be for replacement therapy, **AND**
- Patient must have documented intolerance to levothyroxine sodium; OR
- Patient must have documented resistance to levothyroxine sodium.

Authority required (STREAMLINED)**6475**

Hypothyroidism

Clinical criteria:

- The condition must be severe hypothyroidism, **AND**

- The treatment must be for initiation of therapy only.

liothyronine sodium 20 microgram tablet, 100

2318B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	68.42	40.30	Tertroxin [QA]

ANTITHYROID PREPARATIONS*Thiouracils***■ PROPYLTHIOURACIL****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.

propylthiouracil 50 mg tablet, 100

1955X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*42.95	40.30	PTU [FF]

*Sulfur-containing imidazole derivatives***■ CARBIMAZOLE****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.

carbamazole 5 mg tablet, 100

1153Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*39.07	40.30	Neo-Mercazole [GH]

■ PANCREATIC HORMONES**GLYCOGENOLYTIC HORMONES***Glycogenolytic hormones***■ GLUCAGON HYDROCHLORIDE****glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

1449G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	49.12	40.30	GlucaGen Hypokit [NO]

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

5105Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	49.12	40.30	GlucaGen Hypokit [NO]

■ CALCIUM HOMEOSTASIS**PARATHYROID HORMONES AND ANALOGUES***Parathyroid hormones and analogues***■ TERIPARATIDE**

Note No 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 established osteoporosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

Clinical criteria:

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised agent, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

Note Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

Authority required

Severe established osteoporosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

Note Up to a maximum of 18 pens will be reimbursed through the PBS.

teriparatide 250 microgram/mL injection, 2.4 mL pen device

9411H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	412.19	40.30	Forteo [LY]

ANTI-PARATHYROID AGENTS

Calcitonin preparations

■ CALCITONIN SALMON (SALCATONIN)

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.

Restricted benefit

Symptomatic Paget disease of bone

Restricted benefit

Hypercalcaemia

Clinical criteria:

- The treatment must be initiated in a hospital.

calcitonin salmon (salcatonin) 100 units/mL injection, 5 x 1 mL ampoules

2997R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*125.68	40.30	Miacalcic 100 [EU]

■ ANTIINFECTIVES FOR SYSTEMIC USE

■ ANTIBACTERIALS FOR SYSTEMIC USE

TETRACYCLINES

Tetracyclines

■ DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

doxycycline 100 mg modified release capsule, 7

2708M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	^B 1.54	14.48	14.19	^a Mayne Pharma Doxycycline [YT]
			^B 2.96	15.90	14.19	^a Doryx [YN]

doxycycline 100 mg modified release capsule, 7

3322W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	^B 1.54	14.48	14.19	^a Mayne Pharma Doxycycline [YT]
			^B 2.96	15.90	14.19	^a Doryx [YN]

doxycycline 100 mg tablet, 7

2709N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	12.94	14.19	^a Doxsig [RW] ^a Doxylin 100 [AF]	^a Doxycycline AN [EA]

doxycycline 100 mg tablet, 7

3321T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.94	14.19	^a Doxsig [RW] ^a Doxylin 100 [AF]	^a Doxycycline AN [EA]

doxycycline 100 mg tablet, 7

5082L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.94	14.19	^a APO-Doxycycline [TX] ^a GenRx Doxycycline [GX]	^a Doxycycline Sandoz [HX]

doxycycline 100 mg tablet, 7

9105F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	12.94	14.19	^a APO-Doxycycline [TX] ^a GenRx Doxycycline [GX]	^a Doxycycline Sandoz [HX]

■ DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

Restricted benefit

Urethritis

doxycycline 100 mg tablet, 7

2714W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	..	..	*15.85	17.10	^a Doxsig [RW] ^a Doxylin 100 [AF]	^a Doxycycline AN [EA]

doxycycline 100 mg tablet, 7

9108J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	..	..	*15.85	17.10	^a Doxycycline Sandoz [HX]

doxycycline 100 mg tablet, 21

10176N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.87	17.12	^a Doxycycline AN [EA]	^a Doxylin 100 [AF]

doxycycline 100 mg tablet, 21

1800R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.87	17.12	^a APO-Doxycycline [TX]	^a GenRx Doxycycline [GX]

doxycycline 100 mg modified release capsule, 21

2715X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	^B 3.21	19.08	17.12	^a Mayne Pharma Doxycycline [YT]
			^B 9.00	24.87	17.12	^a Doryx [YN]

■ DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

Restricted benefit

Severe acne

doxycycline 100 mg modified release capsule, 7

10777F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	^B 6.16	*23.47	18.56	^a Mayne Pharma Doxycycline [YT]
			^B 11.84	*29.15	18.56	^a Doryx [YN]

doxycycline 100 mg tablet, 7

10779H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*17.31	18.56	^a Doxsig [RW]	^a Doxycycline AN [EA]

^a Doxylin 100 [AF]**doxycycline 100 mg tablet, 7**

10781K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*17.31	18.56	^a APO-Doxycycline [TX] ^a GenRx Doxycycline [GX]	^a Doxycycline Sandoz [HX]

DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

Restricted benefit

Pelvic inflammatory disease

doxycycline 100 mg modified release capsule, 7

2703G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	..	^B 6.16	*23.47	18.56	^a Mayne Pharma Doxycycline [YT]	
			^B 11.84	*29.15	18.56	^a Doryx [YN]	

doxycycline 100 mg tablet, 7

2702F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	..	..	*17.31	18.56	^a Doxsig [RW] ^a Doxylin 100 [AF]	^a Doxycycline AN [EA]

doxycycline 100 mg tablet, 7

9107H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	..	..	*17.31	18.56	^a APO-Doxycycline [TX] ^a GenRx Doxycycline [GX]	^a Doxycycline Sandoz [HX]

DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hydrochloride), doxycycline tablet 50 mg (as monohydrate) and doxycycline capsule: modified release 50 mg (as hydrochloride) are equivalent for the purposes of substitution.

Restricted benefit

Bronchiectasis

Population criteria:

- Patient must be aged 8 years or older.

Restricted benefit

Chronic bronchitis

Population criteria:

- Patient must be aged 8 years or older.

Restricted benefit

Severe acne

doxycycline 50 mg modified release capsule, 25

2707L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	^B 2.59	16.40	15.06	^a Mayne Pharma Doxycycline [YT]	
			^B 5.01	18.82	15.06	^a Doryx [YN]	

doxycycline 50 mg tablet, 25

2711Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.81	15.06	^a Doxycycline AN [EA]	^a Doxylin 50 [AF]

doxycycline 50 mg tablet, 25

9106G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.81	15.06	^a APO-Doxycycline [TX] ^a Frakas [RW]	^a Doxycycline Sandoz [HX] ^a GenRx Doxycycline [GX]

MINOCYCLINE

Caution There are concerns about the incidence of benign intracranial hypertension associated 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.

Restricted benefit

Severe acne

Clinical criteria:

- The condition must not be responding to other tetracyclines.

ANTIINFECTIVES FOR SYSTEMIC USE

minocycline 50 mg tablet, 60

1616C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.98	20.23	^a Akamin 50 [AF]
			^B 1.65	20.63	20.23	^a Minomycin-50 [QA]

BETA-LACTAM ANTIBACTERIALS, PENICILLINS

Penicillins with extended spectrum

AMOXICILLIN

amoxicillin 250 mg capsule, 20

1884E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	1	..	12.95	14.20	^a Alphamox 250 [AF]	^a AMILOXYN [RF]
						^a Amoxycillin AN [EA]	^a Amoxycillin Ranbaxy [RA]
						^a Amoxycillin Sandoz [SZ]	^a APO-Amoxycillin [TX]
						^a Cilamox [QA]	
			^B 3.49	16.44	14.20	^a Amoxil [AS]	

amoxicillin 250 mg capsule, 20

3301R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.95	14.20	^a Alphamox 250 [AF]	^a AMILOXYN [RF]
						^a Amoxycillin AN [EA]	^a Amoxycillin Ranbaxy [RA]
						^a Amoxycillin Sandoz [SZ]	^a APO-Amoxycillin [TX]
						^a Cilamox [QA]	
			^B 3.49	16.44	14.20	^a Amoxil [AS]	

amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL

1887H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	1	..	#16.02	17.63	^a Alphamox 250 [AF]	^a Amoxycillin Sandoz [SZ]
						^a APO-Amoxycillin [TX]	^a Cilamox [QA]
			^B 3.56	#19.58	17.63	^a Amoxil Forte [AS]	

amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL

3393N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#16.02	17.63	^a Alphamox 250 [AF]	^a Amoxycillin Sandoz [SZ]
						^a APO-Amoxycillin [TX]	^a Cilamox [QA]
			^B 3.56	#19.58	17.63	^a Amoxil Forte [AS]	

amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL

1886G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	1	..	#15.69	17.30	^a Alphamox 125 [AF]	^a Amoxycillin Sandoz [SZ]
						^a APO-Amoxycillin [TX]	
			^B 3.46	#19.15	17.30	^a Amoxil [AS]	

amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL

3302T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#15.69	17.30	^a Alphamox 125 [AF]	^a Amoxycillin Sandoz [SZ]
						^a APO-Amoxycillin [TX]	
			^B 3.46	#19.15	17.30	^a Amoxil [AS]	

amoxicillin 100 mg/mL powder for oral liquid, 20 mL

1888J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	^S 0.53	#21.16	22.24	Amoxil [AS]

amoxicillin 100 mg/mL powder for oral liquid, 20 mL

3310F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	^S 0.53	#21.16	22.24	Amoxil [AS]

amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL

5225B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	#16.12	17.73	Maxamox [SZ]

amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL

8705E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	#16.12	17.73	Maxamox [SZ]

amoxicillin 500 mg capsule, 20

1889K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	1	..	13.23	14.48	^a Alphamox 500 [AF]	^a AMILOXYN [RF]
						^a Amoxycillin AN [EA]	^a Amoxycillin generichealth 500 [GQ]

						^a Amoxycillin Ranbaxy [RA]	^a Amoxycillin Sandoz [SZ]
						^a APO-Amoxycillin [TX]	^a Cilamox [QA]
			^B 3.76	16.99	14.48	^a Amoxil [AS]	
amoxicillin 500 mg capsule, 20							
3300Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.23	14.48	^a Alphamox 500 [AF]	^a AMILOXYN [RF]
						^a Amoxycillin AN [EA]	^a Amoxycillin generichealth 500 [GQ]
						^a Amoxycillin Ranbaxy [RA]	^a Amoxycillin Sandoz [SZ]
						^a APO-Amoxycillin [TX]	^a Cilamox [QA]
			^B 3.76	16.99	14.48	^a Amoxil [AS]	

AMOXICILLIN

Restricted benefit

Chronic bronchitis

Clinical criteria:

- Patient must have acute exacerbations of the condition.

amoxicillin 1 g tablet, 14

8581P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	13.06	14.31	^a Amoxycillin Sandoz [BG]
			^B 1.08	14.14	14.31	^a Maxamox [SZ]

AMOXICILLIN

Authority required

Infection suspected or proven to be due to a susceptible organism

Clinical criteria:

- The treatment must be for patients who require a liquid formulation and in whom the syrup formulations are unsuitable.

amoxicillin 100 mg/mL powder for oral liquid, 20 mL

9714G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	#21.16	22.77	Amoxil [AS]

AMPICILLIN

ampicillin 1 g injection, 5 vials

2977Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.62	18.87	^a Ampicyn [AF]	^a Austrapen [AL]

ampicillin 1 g injection, 5 vials

3314K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	17.62	18.87	^a Ampicyn [AF]	^a Austrapen [AL]

ampicillin 500 mg injection, 5 vials

2390T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	16.44	17.69	Austrapen [AL]

ampicillin 500 mg injection, 5 vials

3313J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	16.44	17.69	Austrapen [AL]

Beta-lactamase sensitive penicillins

BENZATHINE BENZYL PENICILLIN

benzathine benzylpenicillin tetrahydrate 600 000 units (517 mg)/1.17 mL injection, 10 x 1.17 mL syringes

11723B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	153.27	40.30	Bicillin L-A [PF]

benzathine benzylpenicillin tetrahydrate 600 000 units (517 mg)/1.17 mL injection, 10 x 1.17 mL syringes

11735P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	153.27	40.30	Bicillin L-A [PF]

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

2267H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	298.66	40.30	Bicillin L-A [PF]

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

5027N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	298.66	40.30	Bicillin L-A [PF]

■ BENZYL PENICILLIN

benzylpenicillin 3 g injection, 1 vial

2647H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	..	..	*107.29	40.30	BenPen [CS]

benzylpenicillin 3 g injection, 1 vial

3399X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	10	..	..	*107.29	40.30	BenPen [CS]

benzylpenicillin 600 mg injection, 1 vial

1775K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	10	1	..	*70.89	40.30	BenPen [CS]

benzylpenicillin 600 mg injection, 1 vial

3398W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	10	..	..	*70.89	40.30	BenPen [CS]

■ PHENOXYMETHYLPENICILLIN

phenoxymethylpenicillin 500 mg capsule, 50

2965C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.61	18.86	Cilicaine VK [FM]	LPV [IL]

phenoxymethylpenicillin 500 mg capsule, 50

3364C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	17.61	18.86	Cilicaine VK [FM]	LPV [IL]

phenoxymethylpenicillin 500 mg tablet, 25

3028J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*17.79	19.04	Aspecillin VK [QA]

phenoxymethylpenicillin 500 mg tablet, 25

3361X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*17.79	19.04	Aspecillin VK [QA]

phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

5029Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*#23.30	24.91	Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

8977L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*#23.30	24.91	Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL

5012T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*24.69	25.94	Cilicaine V [FM]

phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL

9143F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*24.69	25.94	Cilicaine V [FM]

phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL

5024K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*#21.06	22.67	Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL

8976K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*#21.06	22.67	Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 250 mg capsule, 50

1789E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.60	16.85	Cilicaine VK [FM]	LPV [IL]

phenoxymethylpenicillin 250 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3363B DP	1	..	..	15.60	16.85	Cilicaine VK [FM]	LPV [IL]

phenoxymethylpenicillin 250 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1787C NP	2	..	..	*15.75	17.00	Aspecillin VK [QA]	

phenoxymethylpenicillin 250 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3360W DP	2	..	..	*15.75	17.00	Aspecillin VK [QA]	

■ PHENOXYMETHYLPENICILLIN**Restricted benefit**

Recurrent streptococcal infections (including rheumatic fever)

Clinical criteria:

- The treatment must be for prophylaxis.

phenoxymethylpenicillin 250 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1705R NP	1	5	..	15.60	16.85	Cilicaine VK [FM]	LPV [IL]

phenoxymethylpenicillin 250 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1703P NP	2	5	..	*15.75	17.00	Aspecillin VK [QA]	

■ PROCAINE BENZYL PENICILLIN (PROCAINE PENICILLIN)**procaine benzylpenicillin (procaine penicillin) 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1794K NP	1	..	..	74.83	40.30	Cilicaine [QA]	

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

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
3371K DP	1	..	..	74.83	40.30	Cilicaine [QA]	

*Beta-lactamase resistant penicillins***■ DICLOXACILLIN****Restricted benefit**

Serious staphylococcal infection

dicloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5097G DP	1	..	..	19.58	20.83	^a Dicloxacillin Mylan 500 [AL]	^a Distaph 500 [AF]

dicloxacillin 250 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5096F DP	1	..	..	16.10	17.35	^a Dicloxacillin Mylan 250 [AL]	^a Distaph 250 [AF]

■ DICLOXACILLIN**Restricted benefit**

Serious staphylococcal infection

dicloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8122L NP MW	1	..	..	19.58	20.83	^a Dicloxacillin Mylan 500 [AL]	^a Distaph 500 [AF]

dicloxacillin 250 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8121K NP MW	1	..	..	16.10	17.35	^a Dicloxacillin Mylan 250 [AL]	^a Distaph 250 [AF]

■ DICLOXACILLIN**Authority required (STREAMLINED)****6188**

Osteomyelitis

dicloxacillin 500 mg capsule, 24

10790X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*27.69	28.94	^a Dicloxacillin Mylan 500 [AL]	^a Distaph 500 [AF]

FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Note Pharmaceutical benefits that have the form flucloxacillin 1 g injection in a pack size of 5 can be substituted for a pack size of 10 in the case of a shortage.

flucloxacillin 1 g injection, 5 vials

1525G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	20.06	21.31	^a Flucil [AS]

flucloxacillin 1 g injection, 5 vials

5095E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	20.06	21.31	^a Flucil [AS]

flucloxacillin 1 g injection, 10 vials

10605E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	0.5	1	..	*24.10	25.35	^a Flubiclox [JU]	^a Hospira Pty Limited [PF]

flucloxacillin 1 g injection, 10 vials

10609J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	0.5	..	..	*24.10	25.35	^a Flubiclox [JU]	^a Hospira Pty Limited [PF]

FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL

5257Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	#20.44	22.05	Flucil [LN]

flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL

5258R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	#23.51	25.12	Flucil [LN]

FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL

9149M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	#20.44	22.05	Flucil [LN]

flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL

9150N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	#23.51	25.12	Flucil [LN]

FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Note Pharmaceutical benefits that have the form flucloxacillin 500 mg capsule, 24 and pharmaceutical benefits that have the form flucloxacillin 500 mg capsule, 100 are equivalent for the purposes of substitution.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 500 mg capsule, 24

5091Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	20.17	21.42	^a APO-Flucloxacillin [TX] ^a Staphylex 500 [AF]	^a Flopen [AS]

flucloxacillin 500 mg capsule, 100

11728G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	0.2	..	..	*34.60	35.85	^a Medsurge [DZ]

■ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Note Pharmaceutical benefits that have the form flucloxacillin 500 mg capsule, 24 and pharmaceutical benefits that have the form flucloxacillin 500 mg capsule, 100 are equivalent for the purposes of substitution.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 500 mg capsule, 24

1527J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	20.17	21.42	^a APO-Flucloxacillin [TX] ^a Staphylex 500 [AF]	^a Flopen [AS]

flucloxacillin 500 mg capsule, 100

11738T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	0.2	..	..	*34.60	35.85	^a Medsurge [DZ]

■ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Note Pharmaceutical benefits that have the form flucloxacillin 250 mg capsule, 28 and pharmaceutical benefits that have the form flucloxacillin 250 mg capsule, 24 are equivalent for the purposes of substitution.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 250 mg capsule, 24

5090X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	15.63	16.88	^a APO-Flucloxacillin [TX] ^a Staphylex 250 [AF]	^a Flopen [AS]

flucloxacillin 250 mg capsule, 28

11733M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	0.9	..	..	*32.10	33.35	^a Medsurge [DZ]

■ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Note Pharmaceutical benefits that have the form flucloxacillin 250 mg capsule, 28 and pharmaceutical benefits that have the form flucloxacillin 250 mg capsule, 24 are equivalent for the purposes of substitution.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 250 mg capsule, 24

1526H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	15.63	16.88	^a APO-Flucloxacillin [TX] ^a Staphylex 250 [AF]	^a Flopen [AS]

flucloxacillin 250 mg capsule, 28

11746F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	0.9	..	..	*32.10	33.35	^a Medsurge [DZ]

■ FLUCLOXACILLIN

Caution Severe cholestatic jaundice has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Note Pharmaceutical benefits that have the form flucloxacillin 500 mg capsule, 24 and pharmaceutical benefits that have the form flucloxacillin 500 mg capsule, 100 are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

6169

Osteomyelitis

flucloxacillin 500 mg capsule, 24

10788T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*28.87	30.12	^a APO-Flucloxacillin [TX] ^a Staphylex 500 [AF]	^a Flopen [AS]

flucloxacillin 500 mg capsule, 100

11737R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	0.5	1	..	*46.18	40.30	^a Medsurge [DZ]

*Combinations of penicillins, incl. beta-lactamase inhibitors***■ AMOXICILLIN + CLAVULANIC ACID****Caution** Hepatotoxicity has been reported with this drug.**Restricted benefit**

Infection where resistance to amoxicillin is suspected

Restricted benefit

Infections where resistance to amoxicillin is proven

amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10

1891M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	1	..	13.95	15.20	^a AlphaClav Duo [AF]	^a AMCLAVOX DUO 500/125 [RW]
						^a AMOXICLAV AMNEAL 500/125 [ED]	^a Amoxyclav AN 500/125 [EA]
						^a APO-Amoxycillin/ Clavulanic Acid 500/125 [TX]	^a Curam Duo 500/125 [SZ]
						^a Moxiclav Duo 500/125 [QA]	
			^B 4.87	18.82	15.20	^a Augmentin Duo [AS]	

amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL

1892N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	#16.03	17.64	Curam [SZ]

amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

8254K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	14.25	15.50	^a AlphaClav Duo Forte [AF]	^a AMCLAVOX DUO FORTE 875/125 [RW]
						^a AMOXICLAV AMNEAL 875/125 [ED]	^a Amoxyclav AN 875/125 [EA]
						^a AmoxyClav generichealth 875/125 [HQ]	^a APO-Amoxycillin and Clavulanic Acid [TX]
						^a Clavam 875 mg/125 mg [CR]	^a Curam Duo Forte 875/125 [SZ]
						^a Moxiclav Duo Forte 875/125 [QA]	
			^B 6.24	20.49	15.50	^a Augmentin Duo forte [AS]	

amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL

8319W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	#16.35	17.96	^a Curam Duo [SZ]
			^B 4.84	#21.19	17.96	^a Augmentin Duo 400 [AS]

■ AMOXICILLIN + CLAVULANIC ACID**Caution** Hepatotoxicity has been reported with this drug.**Restricted benefit**

Infection where resistance to amoxicillin is suspected

Restricted benefit

Infections where resistance to amoxicillin is proven

amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10

5008N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.95	15.20	^a AlphaClav Duo [AF]	^a AMCLAVOX DUO 500/125 [RW]
						^a AMOXICLAV AMNEAL 500/125 [ED]	^a Amoxyclav AN 500/125 [EA]
						^a APO-Amoxycillin/ Clavulanic Acid 500/125 [TX]	^a Curam Duo 500/125 [SZ]
						^a Moxiclav Duo 500/125 [QA]	
			^B 4.87	18.82	15.20	^a Augmentin Duo [AS]	

amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL

5009P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	#16.03	17.64	Curam [SZ]

amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

5006L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	14.25	15.50	^a AlphaClav Duo Forte [AF]	^a AMCLAVOX DUO FORTE 875/125 [RW]

^a AMOXICLAV AMNEAL 875/125 [ED]	^a Amoxyclav AN 875/125 [EA]
^a AmoxyClav generichealth 875/125 [HQ]	^a APO-Amoxycillin and Clavulanic Acid [TX]
^a Clavam 875 mg/125 mg [CR]	^a Curam Duo Forte 875/125 [SZ]
^a Moxiclav Duo Forte 875/125 [QA]	
^a Augmentin Duo forte [AS]	

amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL

5011R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^{DP}	‡1	..	..	#16.35	17.96	^a Curam Duo [SZ]	
			^B 4.84	#21.19	17.96	^a Augmentin Duo 400 [AS]	

OTHER BETA-LACTAM ANTIBACTERIALS

First-generation cephalosporins

■ **CEFALEXIN**

cefalexin 125 mg/5 mL powder for oral liquid, 100 mL

3094W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^{NP}	‡1	1	..	#16.27	17.88	^a Cefalexin Sandoz [SZ]	^a Ibilex 125 [AF]
			^B 4.15	#20.42	17.88	^a Keflex [AS]	

cefalexin 125 mg/5 mL powder for oral liquid, 100 mL

3319Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^{DP}	‡1	..	..	#16.27	17.88	^a Cefalexin Sandoz [SZ]	^a Ibilex 125 [AF]
			^B 4.15	#20.42	17.88	^a Keflex [AS]	

cefalexin 250 mg/5 mL powder for oral liquid, 100 mL

3095X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^{NP}	‡1	1	..	#16.57	18.18	^a Cefalexin Sandoz [SZ]	^a Ibilex 250 [AF]
			^B 5.69	#22.26	18.18	^a Keflex [AS]	

cefalexin 250 mg/5 mL powder for oral liquid, 100 mL

3320R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^{DP}	‡1	..	..	#16.57	18.18	^a Cefalexin Sandoz [SZ]	^a Ibilex 250 [AF]
			^B 5.69	#22.26	18.18	^a Keflex [AS]	

cefalexin 250 mg capsule, 20

3058Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^{NP} ^{MW}	1	1	..	13.19	14.44	^a APO-Cephalexin [TX] ^a Cephalexin AN [EA]	^a Cefalexin Sandoz [SZ] ^a Ibilex 250 [AF]
			^B 3.76	16.95	14.44	^a Keflex [AS]	

cefalexin 250 mg capsule, 20

3317N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^{DP}	1	..	..	13.19	14.44	^a APO-Cephalexin [TX] ^a Cephalexin AN [EA]	^a Cefalexin Sandoz [SZ] ^a Ibilex 250 [AF]
			^B 3.76	16.95	14.44	^a Keflex [AS]	

cefalexin 500 mg capsule, 20

3119E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^{NP} ^{MW}	1	1	..	13.34	14.59	^a APO-Cephalexin [TX] ^a Cephalax 500 [CR] ^a Cephalexin generichealth [GQ]	^a Cefalexin Sandoz [SZ] ^a Cephalaxin AN [EA] ^a Ibilex 500 [AF]
			^B 5.47	18.81	14.59	^a Keflex [AS]	

cefalexin 500 mg capsule, 20

3318P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^{DP}	1	..	..	13.34	14.59	^a APO-Cephalexin [TX] ^a Cephalax 500 [CR] ^a Cephalexin generichealth [GQ]	^a Cefalexin Sandoz [SZ] ^a Cephalaxin AN [EA] ^a Ibilex 500 [AF]
			^B 5.47	18.81	14.59	^a Keflex [AS]	

■ **CEFALEXIN**

Authority required (STREAMLINED)

6188

Osteomyelitis

cefalexin 500 mg capsule, 20

10778G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*15.21	16.46	^a APO-Cephalexin [TX] ^a Cephalax 500 [CR]	^a Cefalexin Sandoz [SZ] ^a Cephalaxin AN [EA]

^B10.94 *26.15 16.46 ^a Cephalixin generichealth [GQ] ^a Ibilex 500 [AF]
^a Keflex [AS]

■ CEFALOXIN

Authority required (STREAMLINED)

4243

Prophylaxis of urinary tract infection

cefalexin 250 mg capsule, 20

2655R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*14.91	16.16	^a APO-Cephalexin [TX]	^a Cefalexin Sandoz [SZ]
						^a Cephalixin AN [EA]	^a Ibilex 250 [AF]
			^B 7.52	*22.43	16.16	^a Keflex [AS]	

■ CEFALOTIN

cefalotin 1 g injection, 10 vials

2964B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	25.95	27.20	Hospira Pty Limited [PF]

cefalotin 1 g injection, 10 vials

3376Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	25.95	27.20	Hospira Pty Limited [PF]

■ CEFAZOLIN

Restricted benefit

Cellulitis

cefazolin 2 g injection, 1 vial

5479J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*39.29	40.30	Cephazolin Alphapharm [AF]

cefazolin 500 mg injection, 5 vials

5477G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*17.79	19.04	Cefazolin-AFT [AE]

■ CEFAZOLIN

Note For item codes 5478H and 1799Q, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

Restricted benefit

Cellulitis

cefazolin 1 g injection, 10 vials

5478H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	21.26	22.51	^a Cefazolin Sandoz [SZ]

cefazolin 1 g injection, 5 vials

1799Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*21.27	22.52	^a Cefazolin-AFT [AE]

■ CEFAZOLIN

Note Shared Care Model:

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

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

cefazolin 2 g injection, 1 vial

9326W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*39.29	40.30	Cephazolin Alphapharm [AF]

cefazolin 500 mg injection, 5 vials

1256D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*17.79	19.04	Cefazolin-AFT [AE]

■ CEFAZOLIN

Note For item codes 1257E and 1797N, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

Note Shared Care Model:

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

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

cefazolin 1 g injection, 10 vials

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1257E	1	..	..	21.26	22.51	^a Cefazolin Sandoz [SZ]

cefazolin 1 g injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1797N	2	..	..	*21.27	22.52	^a Cefazolin-AFT [AE]

Second-generation cephalosporins

■ CEFACLOR

Caution Serum sickness-like reactions have been reported with this drug, especially in children.

cefactor 375 mg modified release tablet, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1169M	1	1	..	15.24	16.49	^a APO-Cefaclor CD [TX]	^a Cefaclor GH [GQ]
						^a Karlor CD [LN]	^a Keflor CD [AF]
			^B 6.26	21.50	16.49	^a Ceclor CD [AS]	

cefactor 375 mg modified release tablet, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5045M	1	..	..	15.24	16.49	^a APO-Cefaclor CD [TX]	^a Cefaclor GH [GQ]
						^a Karlor CD [LN]	^a Keflor CD [AF]
			^B 6.26	21.50	16.49	^a Ceclor CD [AS]	

cefactor 250 mg/5 mL powder for oral liquid, 75 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2461M	‡1	1	..	#17.87	19.48	^a Aclor 250 [QA]	^a APO-Cefaclor [TX]
						^a Keflor [AF]	
			^B 5.31	#23.18	19.48	^a Ceclor [AS]	

cefactor 250 mg/5 mL powder for oral liquid, 75 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5047P	‡1	..	..	#17.87	19.48	^a Aclor 250 [QA]	^a APO-Cefaclor [TX]
						^a Keflor [AF]	
			^B 5.31	#23.18	19.48	^a Ceclor [AS]	

cefactor 125 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2460L	‡1	1	..	#17.65	19.26	^a Aclor 125 [QA]	^a APO-Cefaclor [TX]
						^a Keflor [AF]	
			^B 5.10	#22.75	19.26	^a Ceclor [AS]	

cefactor 125 mg/5 mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5046N	‡1	..	..	#17.65	19.26	^a Aclor 125 [QA]	^a APO-Cefaclor [TX]
						^a Keflor [AF]	
			^B 5.10	#22.75	19.26	^a Ceclor [AS]	

■ CEFUROXIME

cefuroxime 125 mg/5 mL powder for oral liquid, 70 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2002J	‡1	..	..	#22.91	24.52	Zinnat [AS]

cefuroxime 125 mg/5 mL powder for oral liquid, 70 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5499K	‡1	1	..	#22.91	24.52	Zinnat [AS]

cefuroxime 250 mg tablet, 14

5052X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	21.57	22.82	Pharmacor Cefuroxime [CR]

cefuroxime 250 mg tablet, 14

8292K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	21.57	22.82	Pharmacor Cefuroxime [CR]

cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL

11191B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	#26.60	28.21	Zinnat [AS]

cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL

11192C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	#26.60	28.21	Zinnat [AS]

cefuroxime 250 mg tablet, 20

11227X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	25.89	27.14	^a Pharmacor Cefuroxime [CR]	^a Zinnat [AS]

cefuroxime 250 mg tablet, 20

11228Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	25.89	27.14	^a Pharmacor Cefuroxime [CR]	^a Zinnat [AS]

*Third-generation cephalosporins***▪ CEFOTAXIME****Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

cefotaxime 1 g injection, 10 vials

1768C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	27.50	28.75	Hospira Pty Limited [PF]

▪ CEFOTAXIME**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

cefotaxime 2 g injection, 10 vials

1769D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	35.13	36.38	Hospira Pty Limited [PF]

▪ CEFOTAXIME**Note Shared Care Model:**

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

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

cefotaxime 2 g injection, 10 vials

1759N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	35.13	36.38	Hospira Pty Limited [PF]

cefotaxime 1 g injection, 10 vials

1758M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	27.50	28.75	Hospira Pty Limited [PF]

▪ CEFTRIAXONE**Restricted benefit**

Gonorrhoea

ceftriaxone 500 mg injection, 1 vial

9058R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	12.54	13.79	Ceftriaxone-AFT [AE]

■ CEFTRIAXONE

Note Shared Care Model:

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

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

ceftriaxone 500 mg injection, 1 vial

1783W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	..	..	*16.79	18.04	Ceftriaxone-AFT [AE]

■ CEFTRIAXONE

Note Pharmaceutical benefits that have the form ceftriaxone 2 g injection, 1 vial and pharmaceutical benefits that have the form ceftriaxone 2 g injection, 5 vials are equivalent for the purposes of substitution.

Note Shared Care Model:

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

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

ceftriaxone 2 g injection, 5 vials

11169W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	22.61	23.86	^a Ceftriaxone Alphapharm [AF]

ceftriaxone 2 g injection, 1 vial

1785Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	..	..	*22.64	23.89	^a Ceftriaxone-AFT [AE]

■ CEFTRIAXONE

Note For item codes 1784X and 1788D, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

Note Shared Care Model:

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

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

ceftriaxone 1 g injection, 1 vial

1784X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	..	..	*22.49	23.74	^a Ceftriaxone-AFT [AE]	^a Ceftriaxone Sandoz [SZ]

ceftriaxone 1 g injection, 5 vials

1788D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	22.50	23.75	^a Ceftriaxone Alphapharm [AF]

Fourth-generation cephalosporins

■ CEFEPIME

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.

Authority required

Febrile neutropenia

cefepime 2 g injection, 1 vial

8316Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	10	..	..	*81.09	40.30	^a Cefepime-AFT [AE] ^a Cefepime Kabi [PK] ^a Omegapharm Pty Ltd [OE]	^a Cefepime Alphapharm [AF] ^a DBL Cefepime [PF]

cefepime 1 g injection, 1 vial

8315P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	10	..	..	*51.59	40.30	^a Cefepime-AFT [AE] ^a Cefepime Kabi [PK] ^a Omegapharm Pty Ltd [OE]	^a Cefepime Alphapharm [AF] ^a DBL Cefepime [PF]

SULFONAMIDES AND TRIMETHOPRIM*Trimethoprim and derivatives***■ TRIMETHOPRIM****trimethoprim 300 mg tablet, 7**

2922T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	13.18	14.43	^a Alprim [AF]
			^B 3.68	16.86	14.43	^a Triprim [RW]

■ TRIMETHOPRIM**Authority required (STREAMLINED)****4243**

Prophylaxis of urinary tract infection

trimethoprim 300 mg tablet, 7

2666H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*14.89	16.14	^a Alprim [AF]
			^B 7.36	*22.25	16.14	^a Triprim [RW]

■ TRIMETHOPRIM**Restricted benefit**

Prostatitis

trimethoprim 300 mg tablet, 7

10785P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*18.27	19.52	^a Alprim [AF]
			^B 14.72	*32.99	19.52	^a Triprim [RW]

*Combinations of sulfonamides and trimethoprim, incl. derivatives***■ TRIMETHOPRIM + SULFAMETHOXAZOLE****Caution** There is an increased risk of severe adverse reactions with this combination in the elderly.**trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL**

3103H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	19.78	21.03	Seprin [RW]

trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL

3391L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	19.78	21.03	Seprin [RW]

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

2951H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	13.37	14.62	^a Resprim Forte [AF]
			^B 2.17	15.54	14.62	^a Bactrim DS [RO]
			^B 4.17	17.54	14.62	^a Seprin Forte [RW]

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

3390K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	13.37	14.62	^a Resprim Forte [AF]
			^B 2.17	15.54	14.62	^a Bactrim DS [RO]
			^B 4.17	17.54	14.62	^a Seprin Forte [RW]

■ TRIMETHOPRIM + SULFAMETHOXAZOLE**Caution** There is an increased risk of severe adverse reactions with this combination in the elderly.**Authority required (STREAMLINED)****6201**

Prophylaxis of Pneumocystis jiroveci pneumonia

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

10784N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	2	..	*17.14	18.39	^a Resprim Forte [AF]
			^B 6.51	*23.65	18.39	^a Bactrim DS [RO]
			^B 12.51	*29.65	18.39	^a Septrin Forte [RW]

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS**Macrolides****■ AZITHROMYCIN**

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

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

Restricted benefit

Trachoma

azithromycin 200 mg/5 mL powder for oral liquid, 15 mL

8201P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	#26.75	28.36	Zithromax [PF]

azithromycin 500 mg tablet, 2

8336R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	15.76	17.01	^a APO-Azithromycin [TX] ^a Azithromycin Sandoz [SZ] ^a Terry White Chemists Azithromycin [TW] ^a Zithromax [PF]	^a Azithromycin Mylan [AF] ^a Chem mart Azithromycin [CH] ^a ZITHRO [RW]

■ AZITHROMYCIN

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

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

Restricted benefit

Urethritis

Clinical criteria:

- The condition must be uncomplicated and due to Chlamydia trachomatis.

Restricted benefit

Cervicitis

Clinical criteria:

- The condition must be uncomplicated and due to Chlamydia trachomatis.

azithromycin 500 mg tablet, 2

8200N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.76	17.01	^a APO-Azithromycin [TX] ^a Azithromycin Sandoz [SZ] ^a Terry White Chemists Azithromycin [TW] ^a Zithromax [PF]	^a Azithromycin Mylan [AF] ^a Chem mart Azithromycin [CH] ^a ZITHRO [RW]

■ CLARITHROMYCIN**clarithromycin 250 mg tablet, 14**

8318T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	14.44	15.69	^a APO-Clarithromycin [TX] ^a Clarihexal [HX] ^a Clarithromycin AN [EA] ^a Kalixocin [AF]	^a Clarac [ED] ^a Clarithro 250 [RW] ^a Clarithromycin Sandoz [SZ]
			^B 3.49	17.93	15.69	^a Klacid [GO]	

■ CLARITHROMYCIN**Restricted benefit**

Bordetella pertussis

Restricted benefit

Atypical mycobacterial infections

clarithromycin 250 mg/5 mL powder for oral liquid, 50 mL

9192T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	#30.42	32.03	Klacid [GO]

■ ERYTHROMYCIN

erythromycin 250 mg enteric capsule, 25

1404X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	16.26	17.51	^a Mayne Pharma Erythromycin [YT]
			^B 2.53	18.79	17.51	^a Eryc [YN]

erythromycin 250 mg enteric capsule, 25

3325B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	16.26	17.51	^a Mayne Pharma Erythromycin [YT]
			^B 2.53	18.79	17.51	^a Eryc [YN]

■ ERYTHROMYCIN

Authority required (STREAMLINED)

6160

Severe acne

Clinical criteria:

- The condition must be one in which tetracycline therapy is inappropriate.

erythromycin 250 mg enteric capsule, 25

10780J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*21.05	22.30	^a Mayne Pharma Erythromycin [YT]
			^B 5.06	*26.11	22.30	^a Eryc [YN]

■ ERYTHROMYCIN ETHYLSUCCINATE

erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL

2428T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	#20.42	22.03	E-Mycin 400 [AF]

erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL

3337P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	±1	..	..	#20.42	22.03	E-Mycin 400 [AF]

erythromycin (as ethylsuccinate) 400 mg tablet, 25

2750R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	16.38	17.63	E-Mycin [AF]

erythromycin (as ethylsuccinate) 400 mg tablet, 25

3336N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	16.38	17.63	E-Mycin [AF]

erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL

2424N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	#19.11	20.72	E-Mycin 200 [AF]

erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL

3334L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	±1	..	..	#19.11	20.72	E-Mycin 200 [AF]

■ ERYTHROMYCIN ETHYLSUCCINATE

Authority required (STREAMLINED)

6160

Severe acne

Clinical criteria:

- The condition must be one in which tetracycline therapy is inappropriate.

erythromycin (as ethylsuccinate) 400 mg tablet, 25

10789W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*21.29	22.54	E-Mycin [AF]

■ ROXITHROMYCIN

roxithromycin 150 mg tablet, 10

1760P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	13.96	15.21	^a APO-Roxithromycin [TX]	^a Biaxsig [AV]
						^a Chem mart Roxithromycin [CH]	^a Roxar 150 [RW]

^a Roximycin [AF]
^a Roxithromycin-GA [ED]
^a Terry White Chemists
Roxithromycin [TW]
^a Rulide [SW]
^a Roxithromycin AN [EA]
^a Roxithromycin Sandoz [SZ]

roxithromycin 150 mg tablet, 10

5260W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.96	15.21	^a APO-Roxithromycin [TX] ^a Chem mart Roxithromycin [CH] ^a Roximycin [AF] ^a Roxithromycin-GA [ED] ^a Terry White Chemists Roxithromycin [TW] ^a Rulide [SW]	^a Biaxsig [AV] ^a Roxar 150 [RW] ^a Roxithromycin AN [EA] ^a Roxithromycin Sandoz [SZ]
			^B 2.30	16.26	15.21		

roxithromycin 300 mg tablet, 5

5261X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.96	15.21	^a APO-Roxithromycin [TX] ^a Chem mart Roxithromycin [CH] ^a Roximycin [AF] ^a Roxithromycin-GA [ED] ^a Terry White Chemists Roxithromycin [TW] ^a Rulide [SW]	^a Biaxsig [AV] ^a Roxar 300 [RW] ^a Roxithromycin AN [EA] ^a Roxithromycin Sandoz [SZ]
			^B 2.30	16.26	15.21		

roxithromycin 300 mg tablet, 5

8016X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	13.96	15.21	^a APO-Roxithromycin [TX] ^a Chem mart Roxithromycin [CH] ^a Roximycin [AF] ^a Roxithromycin-GA [ED] ^a Terry White Chemists Roxithromycin [TW] ^a Rulide [SW]	^a Biaxsig [AV] ^a Roxar 300 [RW] ^a Roxithromycin AN [EA] ^a Roxithromycin Sandoz [SZ]
			^B 2.30	16.26	15.21		

roxithromycin 50 mg dispersible tablet, 10

5259T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	17.11	18.36	Rulide D [SW]

roxithromycin 50 mg dispersible tablet, 10

8129W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	17.11	18.36	Rulide D [SW]

Lincosamides

▪ **CLINDAMYCIN**

Restricted benefit

Gram-positive coccal infections

Clinical criteria:

- The condition must not be able to be safely and effectively treated with a penicillin.

clindamycin 150 mg capsule, 24

5057E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	18.35	19.60	^a APO-Clindamycin [TX] ^a Chem mart Clindamycin [CH] ^a Clindamycin LU [LV] ^a Dalacin C [PF]	^a Calindamin [RW] ^a Clindamycin BNM [BZ] ^a Clindamycin [AF] ^a Terry White Chemists Clindamycin [TW]

▪ **CLINDAMYCIN**

Restricted benefit

Gram-positive coccal infections

Clinical criteria:

- The condition must not be able to be safely and effectively treated with a penicillin.

clindamycin 150 mg capsule, 24

3138E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	2	1	..	*25.23	26.48	^a APO-Clindamycin [TX] ^a Chem mart Clindamycin [CH]	^a Calindamin [RW] ^a Clindamycin BNM [BZ]

^a Clindamycin LU [LV]^a Dalacin C [PF]^a Clindamycin [AF]^a Terry White Chemists
Clindamycin [TW]

■ LINCOMYCIN

Note Pharmaceutical benefits that have the form lincomycin 600 mg/2 mL injection, 5 x 2 mL vials and pharmaceutical benefits that have the form lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules are equivalent for the purposes of substitution.

lincomycin 600 mg/2 mL injection, 5 x 2 mL vials

2530E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	..	..	122.16	40.30	^a Lincocin [PF]

lincomycin 600 mg/2 mL injection, 5 x 2 mL vials

5144R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	122.16	40.30	^a Lincocin [PF]

lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules

11366F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	122.16	40.30	^a LINCOMYCIN SXP [XC]

lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules

11380Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	..	..	122.16	40.30	^a LINCOMYCIN SXP [XC]

AMINOGLYCOSIDE ANTIBACTERIALS

Other aminoglycosides

■ GENTAMICIN

gentamicin 80 mg/2 mL injection, 10 x 2 mL ampoules

2824P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	23.00	24.25	Pfizer Australia Pty Ltd [PF]

■ TOBRAMYCIN

Restricted benefit

Pseudomonas aeruginosa infection

Clinical criteria:

- Patient must have cystic fibrosis, **AND**
- The treatment must be systemic.

tobramycin 500 mg/5 mL injection, 10 x 5 mL vials

9480Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	280.17	40.30	Tobra-Day [FF]

■ TOBRAMYCIN

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

tobramycin 80 mg/2 mL injection, 5 x 2 mL vials

1356J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	1	..	*56.65	40.30	^a Hospira Pty Limited [PF]	^a Tobramycin Mylan [AF]

tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5

8872Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	..	*60.95	40.30	Pfizer Australia Pty Ltd [PF]

■ TOBRAMYCIN

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**4456**

Proven Pseudomonas aeruginosa infection

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have cystic fibrosis, **AND**
- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result, **AND**
- Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records.

Population criteria:

- Patient must be 6 years of age or older.

tobramycin 28 mg powder for inhalation, 224 capsules

10066T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2434.97	40.30	TOBI podhaler [GO]

■ TOBRAMYCIN

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**4513**Proven *Pseudomonas aeruginosa* infection

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

Population criteria:

- Patient must be 6 years of age or older.

tobramycin 28 mg powder for inhalation, 224 capsules

10074F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2434.97	40.30	TOBI podhaler [GO]

■ TOBRAMYCIN

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**5520**Proven *Pseudomonas aeruginosa* infection**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- The treatment must be for management.

tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules

5442K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1048.86	40.30	^a Tobo [GO] ^a TOBRAMYCIN SUN [RA] ^a TOBRAMYCIN WOCKHARDT [WC]	^a Tobramycin AN [JU] ^a Tobramycin WKT [LI]

QUINOLONE ANTIBACTERIALS***Fluoroquinolones*****■ CIPROFLOXACIN****Authority required**

Respiratory tract infection

Clinical criteria:

- The condition must be proven or suspected to be caused by *Pseudomonas aeruginosa*, **AND**
- Patient must be severely immunocompromised.

Authority required

Bacterial gastroenteritis

Clinical criteria:

- Patient must be severely immunocompromised.

Authority required

Infection

Clinical criteria:

- The condition must be proven to be due to *Pseudomonas aeruginosa* resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

Authority required

Bone or joint infection

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Epididymo-orchitis

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Prostatitis

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Perichondritis of the pinna

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

ciprofloxacin 750 mg tablet, 14

1210Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	20.91	22.16	^a APO-Ciprofloxacin [TX]	^a C-Flox 750 [AL]
						^a Ciprofloxacin AN [EA]	^a Ciprofloxacin Sandoz [SZ]
						^a Ciprol 750 [RW]	^a Loxip 750 [DO]

ciprofloxacin 500 mg tablet, 14

1209P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.74	18.99	^a APO-Ciprofloxacin [TX]	^a C-Flox 500 [AL]
						^a Cifran [RA]	^a Ciprofloxacin AN [EA]
						^a Ciprofloxacin-BW [GQ]	^a Ciprofloxacin Sandoz [SZ]
						^a Ciprol 500 [RW]	^a Loxip 500 [DO]
			^B 4.58	22.32	18.99	^a Ciproxin 500 [BN]	

■ **CIPROFLOXACIN**

Authority required

Respiratory tract infection

Clinical criteria:

- The condition must be proven or suspected to be caused by *Pseudomonas aeruginosa*, **AND**
- Patient must be severely immunocompromised.

Authority required

Bacterial gastroenteritis

Clinical criteria:

- Patient must be severely immunocompromised.

Authority required

Infection

Clinical criteria:

- The condition must be proven to be due to *Pseudomonas aeruginosa* resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

Authority required

Bone or joint infection

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Epididymo-orchitis

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Prostatitis

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Perichondritis of the pinna

Clinical criteria:

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Gonorrhoea

ciprofloxacin 250 mg tablet, 14

1208N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.68	15.93	^a APO-Ciprofloxacin [TX] ^a Ciprofloxacin Sandoz [SZ]	^a C-Flox 250 [AL] ^a Ciprol 250 [RW]

■ NORFLOXACIN**Authority required**

Acute bacterial enterocolitis

Authority required

Complicated urinary tract infection

norfloxacin 400 mg tablet, 14

3010K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	15.06	16.31	^a GenRx Norfloxacin [GX] ^a Roxin [RW]	^a Nufloxib [AF]

OTHER ANTIBACTERIALS*Glycopeptide antibacterials***■ VANCOMYCIN****Restricted benefit**

Endocarditis

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

vancomycin 1 g injection, 1 vial

2269K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	17.86	19.11	^a Hospira Pty Limited [PF]	^a Vancomycin Alphapharm [AF]

vancomycin 500 mg injection, 1 vial

3130R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*21.57	22.82	Vancomycin Alphapharm [AF]

■ VANCOMYCIN**Restricted benefit**

Endocarditis

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

vancomycin 1 g injection, 1 vial

5083M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	17.86	19.11	^a Hospira Pty Limited [PF]	^a Vancomycin Alphapharm [AF]

vancomycin 500 mg injection, 1 vial

3323X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*21.57	22.82	Vancomycin Alphapharm [AF]

▪ **VANCOMYCIN**

Restricted benefit

Endophthalmitis

Restricted benefit

Infection

Clinical criteria:

- The treatment must be initiated in a hospital, **AND**
- The condition must be one in which vancomycin is an appropriate antibiotic.

vancomycin 1 g injection, 1 vial

2270L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*30.61	31.86	^a Hospira Pty Limited [PF]	^a Vancomycin Alphapharm [AF]

vancomycin 500 mg injection, 1 vial

3131T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*36.69	37.94	Vancomycin Alphapharm [AF]

Steroid antibacterials

▪ **FUSIDATE**

Restricted benefit

Serious staphylococcal infections

Clinical criteria:

- The treatment must be used in combination with another antibiotic, **AND**
- The condition must be proven to be due to a staphylococcus.

sodium fusidate 250 mg tablet, 36

2312Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	84.43	40.30	Fucidin [LO]

▪ **FUSIDATE**

Authority required (STREAMLINED)

6133

Osteomyelitis

Clinical criteria:

- The condition must be methicillin-resistant staphylococcal aureus (MRSA), **AND**
- The treatment must be used in combination with other anti-staphylococcal antibiotics.

sodium fusidate 250 mg tablet, 36

10782L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*157.39	40.30	Fucidin [LO]

Imidazole derivatives

▪ **METRONIDAZOLE**

metronidazole 200 mg tablet, 21

1636D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	12.75	14.00	^a Metrogyl 200 [AF]	^a Metronide 200 [AV]
			^B 2.00	14.75	14.00	^a Flagyl [SW]	

metronidazole 200 mg tablet, 21

3339R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.75	14.00	^a Metrogyl 200 [AF]	^a Metronide 200 [AV]
			^B 2.00	14.75	14.00	^a Flagyl [SW]	

metronidazole 200 mg/5 mL oral liquid, 100 mL

1630T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	22.26	23.51	Flagyl S [SW]

metronidazole 200 mg/5 mL oral liquid, 100 mL

3341W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	22.26	23.51	Flagyl S [SW]

metronidazole 500 mg suppository, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1642K	‡1	..	..	26.04	27.29	Flagyl [SW]

metronidazole 500 mg suppository, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5157K	‡1	..	..	26.04	27.29	Flagyl [SW]

■ METRONIDAZOLE**Restricted benefit**

Anaerobic infections

metronidazole 400 mg tablet, 21

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1621H	1	1	..	14.46	15.71	^a Metrogyl 400 [AF]	^a Metronide 400 [AV]
			^B 2.00	16.46	15.71	^a Flagyl [SW]	

■ METRONIDAZOLE**Restricted benefit**

Anaerobic infections

metronidazole 400 mg tablet, 21

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5155H	1	..	..	14.46	15.71	^a Metrogyl 400 [AF]	^a Metronide 400 [AV]
			^B 2.00	16.46	15.71	^a Flagyl [SW]	

■ TINIDAZOLE**tinidazole 500 mg tablet, 4**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1465D	1	..	..	15.28	16.53	^a Simplotan [FZ]
			^B 6.70	21.98	16.53	^a Fasigyn [PF]

*Nitrofurantoin derivatives***■ NITROFURANTOIN****Caution** Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.**nitrofurantoin 50 mg capsule, 30**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1692C	1	1	..	26.47	27.72	Macrochantin [PF]

nitrofurantoin 100 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1693D	1	1	..	32.51	33.76	Macrochantin [PF]

*Other antibacterials***■ METHENAMINE HIPPURATE****methenamine hippurate 1 g tablet, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3124K	1	5	..	39.71	40.30	Hiprex [IL]

■ ANTIMYCOTICS FOR SYSTEMIC USE**ANTIMYCOTICS FOR SYSTEMIC USE***Triazole derivatives***■ FLUCONAZOLE****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.

Authority required (STREAMLINED)**6002**

Cryptococcal meningitis

Authority required (STREAMLINED)**5978**

Cryptococcal meningitis

Clinical criteria:

- The treatment must be maintenance therapy, **AND**

- Patient must be immunosuppressed.

Authority required (STREAMLINED)

6023

Oropharyngeal candidiasis

Clinical criteria:

- Patient must be immunosuppressed.

Authority required (STREAMLINED)

5989

Oesophageal candidiasis

Clinical criteria:

- Patient must be immunosuppressed.

Authority required (STREAMLINED)

6030

Oropharyngeal candidiasis

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

Authority required (STREAMLINED)

7898

Fungal infection

Clinical criteria:

- The condition must be serious or life-threatening.

fluconazole 400 mg/200 mL injection, 200 mL bag

1757L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	15.72	16.97	Fluconazole Alphapharm [AF]

fluconazole 100 mg/50 mL injection, 50 mL vial

1473M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	7	..	..	*21.46	22.71	Fluconazole Sandoz [SZ]

■ FLUCONAZOLE

Note Not for use in vulvovaginal candida infections.

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.

Authority required (STREAMLINED)

6002

Cryptococcal meningitis

Authority required (STREAMLINED)

5978

Cryptococcal meningitis

Clinical criteria:

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

Authority required (STREAMLINED)

6023

Oropharyngeal candidiasis

Clinical criteria:

- Patient must be immunosuppressed.

Authority required (STREAMLINED)

5989

Oesophageal candidiasis

Clinical criteria:

- Patient must be immunosuppressed.

Authority required (STREAMLINED)

6030

Oropharyngeal candidiasis

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

Authority required (STREAMLINED)

7898

Fungal infection

Clinical criteria:

- The condition must be serious or life-threatening.

fluconazole 50 mg capsule, 28

1471K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.12	23.37	^a Dizole 50 [AF] ^a Ozole [RA]	^a Fluconazole Sandoz [SZ]
			^B 6.00	28.12	23.37	^a Diflucan [PF]	

fluconazole 100 mg capsule, 28

1472L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	32.20	33.45	^a Diflucan [PF] ^a Fluconazole Sandoz [SZ]	^a Dizole 100 [AF] ^a Ozole [RA]

fluconazole 200 mg capsule, 28

1475P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	51.85	40.30	^a APO-Fluconazole [TX] ^a Dizole 200 [AF] ^a Fluconazole Sandoz [SZ] ^a Ozole [RA]	^a Diflucan [PF] ^a Fluconazole APOTEX [GX] ^a Fluzole 200 [RW]

FLUCONAZOLE

Note Not for use in vulvovaginal candida infections.

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.

Authority required (STREAMLINED)**6006**

Cryptococcal meningitis

Clinical criteria:

- Patient must be unable to take a solid dose form of fluconazole.

Authority required (STREAMLINED)**6045**

Cryptococcal meningitis

Clinical criteria:

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

Authority required (STREAMLINED)**6031**

Oropharyngeal candidiasis

Clinical criteria:

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

Authority required (STREAMLINED)**6046**

Oesophageal candidiasis

Clinical criteria:

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

Authority required (STREAMLINED)**6032**

Oropharyngeal candidiasis

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

Authority required (STREAMLINED)**7934**

Fungal infection

Clinical criteria:

- The condition must be serious or life-threatening, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

fluconazole 50 mg/5 mL powder for oral liquid, 35 mL

5446P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	#67.85	40.30	Diflucan [PF]

■ FLUCONAZOLE

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.

Note Pharmaceutical benefits that have the forms fluconazole 200 mg/100 mL injection, 100 mL vial and fluconazole 200 mg/100 mL injection, 100 mL bag are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

6956

Cryptococcal meningitis

Authority required (STREAMLINED)

6978

Cryptococcal meningitis

Clinical criteria:

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

Authority required (STREAMLINED)

6974

Oropharyngeal candidiasis

Clinical criteria:

- Patient must be immunosuppressed.

Authority required (STREAMLINED)

6969

Oesophageal candidiasis

Clinical criteria:

- Patient must be immunosuppressed.

Authority required (STREAMLINED)

6965

Oropharyngeal candidiasis

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

Authority required (STREAMLINED)

7897

Fungal infection

Clinical criteria:

- The condition must be serious or life-threatening.

fluconazole 200 mg/100 mL injection, 100 mL vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1474N	7	..	..	*46.73	40.30	^a Fluconazole Sandoz [SZ]

fluconazole 200 mg/100 mL injection, 100 mL bag

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11139G	7	..	..	*46.73	40.30	^a Fluconazole Alphapharm [AF]

■ ITRACONAZOLE

Note Not for use in vulvovaginal candida infections.

Note One capsule of itraconazole 50 mg (Lozanoc) is therapeutically equivalent to one 100 mg capsule of conventional itraconazole (Sporanox). The recommended dose of Lozanoc is therefore half the recommended dose for Sporanox. Lozanoc 50 mg capsules and Sporanox 100 mg capsules are not interchangeable.

Note Not for use in superficial mycoses

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.

Authority required (STREAMLINED)

6022

Systemic aspergillosis

Authority required (STREAMLINED)

6005

Systemic sporotrichosis

Authority required (STREAMLINED)

6057

Systemic histoplasmosis

Authority required (STREAMLINED)

5988

Disseminated pulmonary histoplasmosis infection
Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

Authority required (STREAMLINED)**6037**

Chronic pulmonary histoplasmosis infection
Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

Authority required (STREAMLINED)**6016**

Oropharyngeal candidiasis

Clinical criteria:

- Patient must be immunosuppressed.

Authority required (STREAMLINED)**6035**

Oesophageal candidiasis

Clinical criteria:

- Patient must be immunosuppressed.

itraconazole 50 mg capsule, 60

10732W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	129.05	40.30	Lozanoc [YN]

itraconazole 100 mg capsule, 60

8196J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	129.05	40.30	^a APO-Itraconazole [TX] ^a ITRANOX [RW]	^a Itracap [AF] ^a Sporanox [JC]

■ POSACONAZOLE

Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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.

Authority required

Invasive aspergillosis

Clinical criteria:

- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

Authority required

Prophylaxis of invasive fungal infections including both yeasts and moulds

Clinical criteria:

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

No more than 6 months therapy per episode will be PBS-subsidised

Authority required

Fungal infection

Clinical criteria:

- The condition must be fusariosis; OR
- The condition must be zygomycosis; OR
- The condition must be coccidioidomycosis; OR
- The condition must be chromoblastomycosis; OR
- The condition must be mycetoma, **AND**
- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

posaconazole 100 mg modified release tablet, 24

10460M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	752.06	40.30	Noxafil [MK]

■ POSACONAZOLE

Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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.

Authority required

Invasive aspergillosis

Clinical criteria:

- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

Authority required

Fungal infection

Clinical criteria:

- The condition must be fusariosis; OR
- The condition must be zygomycosis; OR
- The condition must be coccidioidomycosis; OR
- The condition must be chromoblastomycosis; OR
- The condition must be mycetoma, **AND**
- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

Authority required

Prophylaxis of invasive fungal infections including both yeasts and moulds

Clinical criteria:

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

No more than 6 months therapy per episode will be PBS-subsidised

posaconazole 40 mg/mL oral liquid, 105 mL

9360P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	623.63	40.30	Noxafil [MK]

■ VORICONAZOLE

Note For patients with graft versus host disease, acute myeloid leukaemia or myelodysplastic syndrome, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

Note For patients undergoing allogeneic haematopoietic stem cell transplant, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 2 months' treatment may be authorised.

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.

Authority required

Prophylaxis of invasive fungal infections including both yeasts and moulds

Clinical criteria:

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; OR
- Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment.

voriconazole 50 mg tablet, 56

10173K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	271.57	40.30	^a Vfend [PF] ^a Voriconazole APOTEX [TX] ^a Vttack [AF]	^a Voriconazole APO [GX] ^a Voriconazole Sandoz [SZ] ^a Vzole [RW]

voriconazole 40 mg/mL powder for oral liquid, 70 mL

10168E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	#496.70	40.30	Vfend [PF]

voriconazole 200 mg tablet, 56

10198R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	1068.58	40.30	^a Vfend [PF] ^a Voriconazole APOTEX [TX] ^a Vttack [AF]	^a Voriconazole APO [GX] ^a Voriconazole Sandoz [SZ] ^a Vzole [RW]

■ VORICONAZOLE**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.

Authority required

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- Patient must be immunocompromised.

Authority required

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- The condition must be caused by *Scedosporium* species; OR
- The condition must be caused by *Fusarium* species.

Authority required

Serious *Candida* infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

Authority required

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

voriconazole 50 mg tablet, 56

9363T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	271.57	40.30	^a Vfend [PF] ^a Voriconazole APOTEX [TX] ^a Vttack [AF]	^a Voriconazole APO [GX] ^a Voriconazole Sandoz [SZ] ^a Vzole [RW]

voriconazole 200 mg tablet, 56

9364W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	1068.58	40.30	^a Vfend [PF] ^a Voriconazole APOTEX [TX] ^a Vttack [AF]	^a Voriconazole APO [GX] ^a Voriconazole Sandoz [SZ] ^a Vzole [RW]

■ VORICONAZOLE

Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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.

Authority required

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- Patient must be immunocompromised.

Authority required

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- The condition must be caused by *Scedosporium* species; OR

- The condition must be caused by *Fusarium* species.

Authority required

Serious *Candida* infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

Authority required

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

voriconazole 40 mg/mL powder for oral liquid, 70 mL

9452L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	#496.70	40.30	Vfend [PF]

■ ANTIMYCOBACTERIALS**DRUGS FOR TREATMENT OF TUBERCULOSIS***Hydrazides***■ ISONIAZID****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.

isoniazid 100 mg tablet, 100

1554T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	22.11	23.36	Arrow Pharma Pty Ltd [RW]

DRUGS FOR TREATMENT OF LEPRA*Drugs for treatment of lepra***■ DAPSONE****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.

dapsone 100 mg tablet, 100

1272Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	318.59	40.30	Link Medical Products Pty Ltd [LM]

dapsone 25 mg tablet, 100

8801F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	260.58	40.30	Link Medical Products Pty Ltd [LM]

■ RIFAMPICIN**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.

Authority required

Leprosy

Population criteria:

- Patient must be an adult.

rifampicin 300 mg capsule, 100

1983J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	115.77	40.30	Rimycin 300 [AF]

rifampicin 150 mg capsule, 100

1982H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	241.77	40.30	Rimycin 150 [AF]

■ RIFAMPICIN

Note Shared Care Model:

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

Restricted benefit

Meningococcal disease

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be a carrier of the disease; OR
- Patient must be in close contact with people who have the disease.

Restricted benefit

Haemophilus influenzae type B

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be in contact with people who have the disease.

rifampicin 100 mg/5 mL oral liquid, 60 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8025J	‡1	..	..	28.37	29.62	Rifadin [SW]

rifampicin 300 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1984K	1	..	..	21.91	23.16	Rimycin 300 [AF]

rifampicin 150 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1981G	1	..	..	34.34	35.59	Rimycin 150 [AF]

■ ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

■ ACICLOVIR

Note Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)

5942

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

aciclovir 200 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1007B	1	5	..	36.02	37.27	^a Aciclovir AN [ED] ^a Aciclovir GH [GQ] ^a Acyclo-V 200 [AF] ^a GenRx Aciclovir [GX]	^a Aciclovir APOTEX [TY] ^a Aciclovir Sandoz [HX] ^a APO-Aciclovir [TX] ^a Lovir [EA]

■ ACICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

Note No applications for repeats will be authorised.

Authority required (STREAMLINED)

5967

Herpes zoster

Clinical criteria:

- The treatment must be administered within 72 hours of the onset of the rash.

Authority required (STREAMLINED)

5959

Herpes zoster ophthalmicus

aciclovir 800 mg tablet, 35

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1052J	1	..	..	41.18	40.30	^a Aciclovir APOTEX [TY] ^a APO-Aciclovir [TX]	^a Aciclovir Sandoz [HX] ^a GenRx Aciclovir [GX]

■ ACICLOVIR

Note Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

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

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

Note For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**5936**

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

aciclovir 200 mg tablet, 25

1003T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*25.13	26.38	^a Aciclovir Sandoz [HX]

aciclovir 200 mg tablet, 50

1555W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	25.11	26.36	^a Aciclovir APOTEX [TY] ^a GenRx Aciclovir [GX]	^a APO-Aciclovir [TX]

■ FAMCICLOVIR

Note Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)**5971**

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

famciclovir 250 mg tablet, 56

8217L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	72.33	40.30	^a APO-Famciclovir [TX] ^a Ezovir [AF] ^a Famciclovir-GA [ED] ^a Famciclovir Sandoz [SZ] ^a Famlo [RA] ^a Favic 250 [RW]	^a Auro-Famciclovir 250 [DO] ^a Famciclovir AN [EA] ^a Famciclovir generichealth 250 [GQ] ^a Famciclovir SCP 250 [CR] ^a Famvir [HX]

■ FAMCICLOVIR

Note Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

Note Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)**5937**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

famciclovir 250 mg tablet, 20

2274Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	33.21	34.46	^a APO-Famciclovir [TX] ^a Famciclovir AN [EA] ^a Famciclovir Sandoz [SZ] ^a Favic 250 [RW]	^a Ezovir [AF] ^a Famciclovir-GA [ED] ^a Famvir [HX]

famciclovir 125 mg tablet, 40

8092X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	33.21	34.46	^a APO-Famciclovir [TX] ^a Ezovir [AF] ^a Famciclovir-GA [ED] ^a Favic 125 [RW]	^a Auro-Famciclovir 125 [DO] ^a Famciclovir AN [EA] ^a Famvir [HX]

■ FAMCICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Note No applications for repeats will be authorised.

Authority required (STREAMLINED)

5951

Herpes zoster

Clinical criteria:

- The treatment must be administered within 72 hours of the onset of the rash.

famciclovir 250 mg tablet, 21

8002E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	34.30	35.55	^a APO-Famciclovir [TX] ^a Ezovir [AF] ^a Famciclovir-GA [ED] ^a Famciclovir Sandoz [SZ] ^a Famlo [RA] ^a Favic 250 [RW]	^a Auro-Famciclovir 250 [DO] ^a Famciclovir AN [EA] ^a Famciclovir generichealth 250 [GQ] ^a Famciclovir SCP 250 [CR] ^a Famvir [HX]

■ FAMCICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Note Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

Note No applications for repeats will be authorised.

Authority required (STREAMLINED)**5943**

Herpes zoster

Clinical criteria:

- Patient must be immunocompromised, **AND**
- The treatment must be administered within 72 hours of the onset of the rash.

famciclovir 500 mg tablet, 30

8897G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	44.08	40.30	^a APO-Famciclovir [TX] ^a Famciclovir AN [EA] ^a Famvir [HX]	^a Auro-Famciclovir 500 [DO] ^a Famciclovir Sandoz [SZ] ^a Favic 500 [RW]

■ FAMCICLOVIR

Note Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Note Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

Authority required (STREAMLINED)**5954**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Clinical criteria:

- Patient must be immunocompromised.
- Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

Authority required (STREAMLINED)**5947**

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Episodic treatment

Clinical criteria:

- Patient must have HIV infection, **AND**
- Patient must have a CD4 cell count of less than 500 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

Authority required (STREAMLINED)**5948**

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

Clinical criteria:

- Patient must have HIV infection, **AND**
- Patient must have CD4 cell counts of less than 150 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

Authority required (STREAMLINED)**5949**

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

Clinical criteria:

- Patient must have HIV infection, **AND**
 - Patient must present with other opportunistic infections or AIDS defining tumours.
- Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

famciclovir 500 mg tablet, 56

8896F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	72.34	40.30	^a APO-Famciclovir [TX] ^a Ezovir [AF] ^a Famciclovir-GA [ED] ^a Famciclovir Sandoz [SZ] ^a Favic 500 [RW]	^a Auro-Famciclovir 500 [DO] ^a Famciclovir AN [EA] ^a Famciclovir generichealth 500 [GQ] ^a Famvir [HX]

■ VALACICLOVIR

Note Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)**5940**

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

valaciclovir 500 mg tablet, 30

5480K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.74	26.99	^a APO-Valaciclovir [TX] ^a Vaclovir [AF] ^a Valaciclovir APOTEX [GX] ^a Valaciclovir RBX [RA] ^a Valacor 500 [CR]	^a Shilova 500 [DO] ^a Valaciclovir AN [EA] ^a Valaciclovir generichealth [GQ] ^a Valaciclovir SZ [HX] ^a Zelitrex [RF]
			^b 2.26	28.00	26.99	^a Valtrex [RW]	

■ VALACICLOVIR

Note Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)**5961**

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

valaciclovir 500 mg tablet, 30

8134D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.74	26.99	^a APO-Valaciclovir [TX] ^a Vaclovir [AF] ^a Valaciclovir APOTEX [GX] ^a Valaciclovir RBX [RA] ^a Valaciclovir SZ [HX] ^a Zelitrex [RF]	^a Shilova 500 [DO] ^a Valaciclovir AN [EA] ^a Valaciclovir generichealth [GQ] ^a Valaciclovir Sandoz [SZ] ^a Valacor 500 [CR]
			^b 2.26	28.00	26.99	^a Valtrex [RW]	

■ VALACICLOVIR

Note Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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

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

Authority required (STREAMLINED)**5960**

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

valaciclovir 500 mg tablet, 10

8133C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*20.99	22.24	^a APO-Valaciclovir [TX] ^a Valaciclovir AN [EA] ^a Valaciclovir Sandoz [SZ]	^a Vaclovir [AF] ^a Valaciclovir APOTEX [GX] ^a Zelitrex [RF]
			^b 2.26	*23.25	22.24	^a Valtrex [RW]	

■ VALACICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Note No applications for repeats will be authorised.

Authority required (STREAMLINED)

5962

Herpes zoster

Clinical criteria:

- The treatment must be administered within 72 hours of the onset of the rash.

Authority required (STREAMLINED)

5968

Herpes zoster ophthalmicus

valaciclovir 500 mg tablet, 42

8064K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	31.44	32.69	^a APO-Valaciclovir [TX] ^a Valaciclovir AN [EA] ^a Valaciclovir generichealth [GQ] ^a Valaciclovir Sandoz [SZ] ^a Zelitrex [RF]	^a Valtrex [RW] ^a Valclovir [AF] ^a Valaciclovir APOTEX [GX] ^a Valaciclovir RBX [RA] ^a Valacor 500 [CR]
			^b 2.26	33.70	32.69		

Antivirals for treatment of HCV infections

▪ **DACLATASVIR**

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

daclatasvir 60 mg tablet, 28

10642D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	7818.79	40.30	Daklinza [BQ]

daclatasvir 30 mg tablet, 28

10645G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	7818.79	40.30	Daklinza [BQ]

▪ **DACLATASVIR**

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

daclatasvir 60 mg tablet, 28

10659B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	7818.79	40.30	Daklinza [BQ]

daclatasvir 30 mg tablet, 28

10671P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	7818.79	40.30	Daklinza [BQ]

▪ **ELBASVIR + GRAZOPREVR**

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

elbasvir 50 mg + grazoprevir 100 mg tablet, 28

11011M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	8552.12	40.30	Zepatier [MK]

■ ELBASVIR + GRAZOPREVR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

elbasvir 50 mg + grazoprevir 100 mg tablet, 28

11021C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	8552.12	40.30	Zepatier [MK]

■ GLECAPREVR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84

11344C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	18818.79	40.30	Maviret [VE]

■ GLECAPREVR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84

11353M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	18818.79	40.30	Maviret [VE]

■ GLECAPREVR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**

- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84

11354N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	18818.79	40.30	Maviret [VE]

▪ LEDIPASVIR + SOFOSBUVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10628J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	12652.12	40.30	Harvoni [GI]

▪ LEDIPASVIR + SOFOSBUVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10668L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	12652.12	40.30	Harvoni [GI]

▪ LEDIPASVIR + SOFOSBUVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10670N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	12652.12	40.30	Harvoni [GI]

▪ RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 400 mg tablet, 28

10647J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	316.78	40.30	Ibavyr [IX]

ribavirin 600 mg tablet, 28

10665H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	472.57	40.30	Ibavyr [IX]

■ RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 400 mg tablet, 28

10673R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	316.78	40.30	Ibavyr [IX]

ribavirin 600 mg tablet, 28

10666J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	472.57	40.30	Ibavyr [IX]

■ SOFOSBUVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg tablet, 28

10624E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	12652.12	40.30	Sovaldi [GI]

■ SOFOSBUVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

sofosbuvir 400 mg tablet, 28

10657X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	12652.12	40.30	Sovaldi [GI]

■ SOFOSBUVIR + VELPATASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

11147Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	12652.12	40.30	Epclusa [GI]

■ SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg tablet, 28

11658N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	12652.12	40.30	Vosevi [GI]

Antivirals for treatment of HIV infections, combinations

■ TENOFOVIR + EMTRICITABINE

Note No 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 Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg tablet, tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

7580

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

Clinical criteria:

- The treatment must be for patients at medium to high risk of HIV infection, as defined by the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) Guidelines, **AND**
- Patient must have a negative HIV test result prior to treatment with PBS-subsidised therapy with this drug.

Population criteria:

- Patient must be 18 years or older.

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

11296M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	165.90	40.30	^a Tenofovir Disoproxil Emtricitabine Mylan 300/200 [AF]

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

11276L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	165.90	40.30	^a Tenofovir/Emtricitabine 300/200 APOTEX [TX]	^a Truvada [GI]

tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30

11306C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	165.90	40.30	^a Tenofovir EMT GH [GQ]

■ VACCINES

BACTERIAL VACCINES

Pneumococcal vaccines

■ PNEUMOCOCCAL PURIFIED CAPSULAR POLYSACCHARIDES

Restricted benefit

Prophylaxis of pneumococcal infection

Clinical criteria:

- Patient must have undergone a splenectomy.

Population criteria:

- Patient must be aged 2 years or older.

Restricted benefit

Prophylaxis of pneumococcal infection

Clinical criteria:

- Patient must have Hodgkin's disease; OR
- Patient must have a high risk of contracting pneumococcal infections.

pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 0.5 mL syringe

10210J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	49.24	40.30	Pneumovax 23 [CS]

pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 0.5 mL vial

1903E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	49.24	40.30	Pneumovax 23 [CS]

Tetanus vaccines

■ DIPHTHERIA + TETANUS VACCINE

Note For immunisation of adults and children aged greater than or equal to 8 years.

diphtheria 2 units + tetanus 20 units vaccine injection, 5 x 0.5 mL syringes

8783G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	69.92	40.30	ADT Booster [CS]

■ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

■ ANTINEOPLASTIC AGENTS

ALKYLATING AGENTS

Nitrogen mustard analogues

■ CHLORAMBUCIL

chlorambucil 2 mg tablet, 25

1163F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*133.63	40.30	Leukeran [AS]

■ CYCLOPHOSPHAMIDE

cyclophosphamide 50 mg tablet, 50

1266P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	153.03	40.30	Cyclonex [ZX]

■ MELPHALAN

melphalan 2 mg tablet, 25

2547C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	63.43	40.30	Alkeran [AS]

Alkyl sulfonates

■ BUSULFAN

busulfan 2 mg tablet, 100

1128J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	77.51	40.30	Myleran [AS]

Nitrosoureas

■ CARMUSTINE

Note Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

Restricted benefit

Glioblastoma multiforme

Clinical criteria:

- The condition must be suspected or confirmed at the time of initial surgery.

carmustine 7.7 mg implant, 8

8898H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15023.10	40.30	Gliadel [EI]

Other alkylating agents▪ **TEMOZOLOMIDE****temozolomide 140 mg capsule, 5**

9362R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	169.62	40.30	^a APO-Temozolomide [TX] ^a Temodal [MK] ^a Temozolomide Alphapharm [AF] ^a Temozolomide Juno [JX]	^a Temizole 140 [QA] ^a Temolide [JU] ^a Temozolomide Amneal [JO]

temozolomide 20 mg capsule, 5

8379B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	38.24	39.49	^a APO-Temozolomide [TX] ^a Temolide [JU] ^a Temozolomide Amneal [JO]	^a Temizole 20 [QA] ^a Temozolomide Alphapharm [AF] ^a Temozolomide Juno [JX]

temozolomide 5 mg capsule, 5

8378Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	20.59	21.84	^a APO-Temozolomide [TX] ^a Temolide [JU] ^a Temozolomide Amneal [JO]	^a Temizole 5 [QA] ^a Temozolomide Alphapharm [AF] ^a Temozolomide Juno [JX]

temozolomide 180 mg capsule, 5

2438H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	203.38	40.30	^a APO-Temozolomide [TX] ^a Temolide [JU] ^a Temozolomide Juno [JX]	^a Temodal [MK] ^a Temozolomide Amneal [JO]

temozolomide 100 mg capsule, 5

8380C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	126.15	40.30	^a APO-Temozolomide [TX] ^a Temodal [MK] ^a Temozolomide Alphapharm [AF] ^a Temozolomide Juno [JX]	^a Temizole 100 [QA] ^a Temolide [JU] ^a Temozolomide Amneal [JO]

temozolomide 250 mg capsule, 5

8381D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	287.18	40.30	^a APO-Temozolomide [TX] ^a Temodal [MK] ^a Temozolomide Alphapharm [AF] ^a Temozolomide Juno [JX]	^a Temizole 250 [QA] ^a Temolide [JU] ^a Temozolomide Amneal [JO]

▪ **TEMOZOLOMIDE**

Note Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.

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

Restricted benefit

Glioblastoma multiforme

Treatment criteria:

- Patient must be undergoing concomitant radiotherapy.

temozolomide 140 mg capsule, 5

9361Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*496.21	40.30	^a APO-Temozolomide [TX] ^a Temodal [MK] ^a Temozolomide Alphapharm [AF] ^a Temozolomide Juno [JX]	^a Temizole 140 [QA] ^a Temolide [JU] ^a Temozolomide Amneal [JO]

temozolomide 20 mg capsule, 5

8820F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*91.75	40.30	^a APO-Temozolomide [TX] ^a Temolide [JU]	^a Temizole 20 [QA] ^a Temozolomide Alphapharm [AF]

^a Temozolomide Amneal [JO] ^a Temozolomide Juno [JX]**temozolomide 5 mg capsule, 5**

8819E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*38.80	40.05	^a APO-Temozolomide [TX] ^a Temolide [JU] ^a Temozolomide Amneal [JO]	^a Temizole 5 [QA] ^a Temozolomide Alphapharm [AF] ^a Temozolomide Juno [JX]

temozolomide 180 mg capsule, 5

10062N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*599.80	40.30	^a APO-Temozolomide [TX] ^a Temolide [JU] ^a Temozolomide Juno [JX]	^a Temodal [MK] ^a Temozolomide Amneal [JO]

temozolomide 100 mg capsule, 5

8821G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*361.24	40.30	^a APO-Temozolomide [TX] ^a Temodal [MK] ^a Temozolomide Alphapharm [AF] ^a Temozolomide Juno [JX]	^a Temizole 100 [QA] ^a Temolide [JU] ^a Temozolomide Amneal [JO]

ANTIMETABOLITES*Folic acid analogues***■ METHOTREXATE****methotrexate 2.5 mg tablet, 30**

1622J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	17.31	18.56	Methoblastin [PF]

methotrexate 5 mg/2 mL injection, 5 x 2 mL vials

2396D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	40.33	40.30	Hospira Pty Limited [PF]

methotrexate 10 mg tablet, 15

2272N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	23.58	24.83	Methoblastin [PF]

■ METHOTREXATE**Restricted benefit**

Patients requiring doses greater than 20 mg per week

methotrexate 10 mg tablet, 50

1623K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	51.80	40.30	Methoblastin [PF]

■ METHOTREXATE**Note** For item codes 2395C and 1818Q, pharmaceutical benefits that have the form injection 50 mg in 2 mL are equivalent for the purposes of substitution.**methotrexate 50 mg/2 mL injection, 5 x 2 mL vials**

2395C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	38.90	40.15	^a Hospira Pty Limited [PF]

METHOTREXATE Injection 50 mg in 2 mL, 1

1818Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*38.89	40.14	^a Methotrexate Accord [OD]

*Purine analogues***■ FLUDARABINE****fludarabine phosphate 10 mg tablet, 20**

9184J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	930.99	40.30	Fludara [GZ]

■ MERCAPTOPURINE

mercaptopurine monohydrate 50 mg tablet, 25

1598D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*243.47	40.30	Purinethol [AS]

mercaptopurine monohydrate 20 mg/mL oral liquid, 100 mL

10214N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	373.07	40.30	Allmercap [LM]

■ TIOGUANINE

tioguanine 40 mg tablet, 25

1233X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	188.91	40.30	Lanvis [AS]

Pyrimidine analogues

■ CAPECITABINE

capecitabine 150 mg tablet, 60

8361C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	22.32	23.57	^a Capecitabine AN [JO] ^a Xelocitabine [JU]	^a Capecitabine-DRLA [RZ]

capecitabine 500 mg tablet, 120

8362D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	78.67	40.30	^a Capecitabine Alphapharm [AF] ^a Capecitabine Apotex [TX] ^a Capecitabine Sandoz [SZ] ^a Xelocitabine [JU]	^a Capecitabine AN [JO] ^a Capecitabine-DRLA [RZ] ^a Xelabine [QA]

■ TRIFLURIDINE + TIPIRACIL

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**8195**

Metastatic colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must have previously received treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-vascular endothelial growth factor (anti-VEGF) agent and an anti-epidermal growth factor receptor (anti-EGFR) agent for this condition; OR
- Patient must not be a suitable candidate for treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-VEGF agent and an anti-EGFR agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

Authority required (STREAMLINED)**8183**

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

trifluridine 20 mg + tipiracil 8.19 mg tablet, 20

11524M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*3923.59	40.30	Lonsurf 20/8.19 [SE]

trifluridine 15 mg + tipiracil 6.14 mg tablet, 20

11507P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	2	..	*2273.53	40.30	Lonsurf 15/6.14 [SE]

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

■ VINORELBINE

Authority required

Advanced breast cancer

Clinical criteria:

- Patient must have failed standard prior therapy, which includes an anthracycline.

Authority required

Locally advanced or metastatic non-small cell lung cancer

vinorelbine 30 mg capsule, 1

9010F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	16	2	..	*1879.23	40.30	Navelbine [FB]

vinorelbine 20 mg capsule, 1

9009E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	20	2	..	*1570.59	40.30	Navelbine [FB]

Podophyllotoxin derivatives

■ ETOPOSIDE

etoposide 100 mg capsule, 10

1389D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	384.31	40.30	Vepesid [BQ]

etoposide 50 mg capsule, 20

1396L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	440.42	40.30	Vepesid [BQ]

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES*Anthracyclines and related substances*

■ IDARUBICIN

Restricted benefit

Acute myelogenous leukaemia (AML)

idarubicin hydrochloride 5 mg capsule, 1

2446R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*307.00	40.30	Zavedos [PF]

OTHER ANTINEOPLASTIC AGENTS*Monoclonal antibodies*

■ RITUXIMAB

Authority required (STREAMLINED)**7400**

Previously untreated or relapsed/refractory CD20 positive lymphoid cancer

Treatment Phase: Induction or re-induction therapy

Clinical criteria:

- The treatment must be for induction or re-induction for CD20 positive lymphoma; OR
- The treatment must be for induction or re-induction for CD20 positive chronic lymphocytic leukaemia; OR
- The treatment must be for induction or consolidation for CD20 positive acute lymphoblastic leukaemia, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.

No more than 8 doses in total as per course of treatment will be allowed for lymphoma or chronic lymphocytic leukaemia.

No more than 12 doses in total as per course of treatment will be allowed for acute lymphoblastic leukaemia for induction course (including consolidation course).

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10703H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	2417.61	40.30	Mabthera SC [RO]

■ RITUXIMAB

Note No increase in the maximum number of repeats may be authorised.**Authority required (STREAMLINED)****6011**

Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

- The treatment must be maintenance therapy, **AND**
- Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application, **AND**
- Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10709P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	7	..	2417.61	40.30	Mabthera SC [RO]

▪ **RITUXIMAB**

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

Authority required (STREAMLINED)

7399

Previously untreated or Relapsed/refractory CD20 positive acute lymphoblastic leukaemia

Treatment Phase: Maintenance therapy

Clinical criteria:

- The treatment must be maintenance therapy, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must be in complete remission, **AND**
- Patient must not receive more than 6 doses in total under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10719E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2417.61	40.30	Mabthera SC [RO]

▪ **RITUXIMAB**

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

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

Authority required (STREAMLINED)

6161

Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

- Patient must have demonstrated a partial or complete response to induction treatment with either R-CHOP or R-CVP regimens for previously untreated follicular B-cell Non-Hodgkin's lymphoma, received immediately prior to this current Authority application, **AND**
- Patient must not have received bendamustine induction therapy, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10742J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	11	..	2417.61	40.30	Mabthera SC [RO]

▪ **TRASTUZUMAB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

Clinical criteria:

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

Authority required

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

Clinical criteria:

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10682F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1803.02	40.30	Herceptin SC [RO]

■ TRASTUZUMAB

Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
- Patient must have undergone surgery, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Authority applications for initial treatment must be made in writing and must include:
 - (a) a completed authority prescription form; and
 - (b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:
 - (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
 - (ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

trastuzumab 600 mg/5 mL injection, 5 mL vial

10721G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1803.02	40.30	Herceptin SC [RO]

■ TRASTUZUMAB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must not be in combination with nab-paclitaxel, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the patient has Stage IV disease.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10798H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1803.02	40.30	Herceptin SC [RO]

▪ **TRASTUZUMAB**

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

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

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Where a patient has a break in trastuzumab therapy of more than 1 week from when the last dose was due, authority approval will be granted for a new loading dose.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10803N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1803.02	40.30	Herceptin SC [RO]

▪ **TRASTUZUMAB**

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

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

Authority required

HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10825R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1803.02	40.30	Herceptin SC [RO]

Protein kinase inhibitors

■ AFATINIB

Note Special Pricing Arrangements apply.

Authority required

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

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

afatinib 50 mg tablet, 28

11329G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2876.12	40.30	Giotrif [BY]

afatinib 40 mg tablet, 28

11359W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2876.12	40.30	Giotrif [BY]

afatinib 30 mg tablet, 28

11341X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2876.12	40.30	Giotrif [BY]

afatinib 20 mg tablet, 28

11335N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2876.12	40.30	Giotrif [BY]

■ AFATINIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7613

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

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

Population criteria:

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

afatinib 50 mg tablet, 28

11342Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2876.12	40.30	Giotrif [BY]

afatinib 40 mg tablet, 28

11347F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2876.12	40.30	Giotrif [BY]

afatinib 30 mg tablet, 28

11348G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2876.12	40.30	Giotrif [BY]

afatinib 20 mg tablet, 28

11336P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2876.12	40.30	Giotrif [BY]

ALECTINIB

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

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

Note Special Pricing Arrangements apply.

Authority required

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

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

Authority required

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

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Authority required

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

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 January 2018, **AND**
- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have progressive disease while receiving treatment with this drug for this condition.

Population criteria:

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

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

alectinib 150 mg capsule, 4 x 56

11226W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	6805.20	40.30	Alecensa [RO]

AXITINIB

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 number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7433

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial 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.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

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

axitinib 1 mg tablet, 28

10539Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1120.85	40.30	Inlyta [PF]

axitinib 5 mg tablet, 28

10556N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*5192.13	40.30	Inlyta [PF]

■ AXITINIB

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

Note Special Pricing Arrangements apply.

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.

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 prior 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.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

axitinib 1 mg tablet, 28

10572K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*1120.85	40.30	Inlyta [PF]

axitinib 5 mg tablet, 28

10540R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*5192.13	40.30	Inlyta [PF]

■ CABOZANTINIB

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

Note Special Pricing Arrangements apply.

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.

Authority required (STREAMLINED)

8572

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 prior 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.

cabozantinib 60 mg tablet, 30

11360X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9952.12	40.30	Cabometyx [IS]

cabozantinib 20 mg tablet, 30

11371L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9952.12	40.30	Cabometyx [IS]

cabozantinib 40 mg tablet, 30

11369J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9952.12	40.30	Cabometyx [IS]

■ CABOZANTINIB

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

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 Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7631

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with 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, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

cabozantinib 60 mg tablet, 30

11367G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9952.12	40.30	Cabometyx [IS]

cabozantinib 20 mg tablet, 30

11374P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9952.12	40.30	Cabometyx [IS]

cabozantinib 40 mg tablet, 30

11368H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9952.12	40.30	Cabometyx [IS]

■ CERITINIB

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

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

Note Special Pricing Arrangements apply.

Authority required

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

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

Authority required

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

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

ceritinib 150 mg capsule, 3 x 50

11056X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	7280.42	40.30	Zykadia [NV]

■ COBIMETINIB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)
6839

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must not have progressive disease when treated with a BRAF inhibitor.

cobimetinib 20 mg tablet, 63

11074W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	8190.15	40.30	Cotellic [RO]

■ COBIMETINIB

Note A patient who has had progressive disease when treated with this drug is 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.

Authority required (STREAMLINED)
6803

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

cobimetinib 20 mg tablet, 63

11075X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8190.15	40.30	Cotellic [RO]

■ CRIZOTINIB

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

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

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

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

(1) a completed authority prescription form; and

(2) a completed ALK-Positive Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form, which includes details of ALK gene rearrangement in tumour material by FISH testing.

Authority required

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

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

crizotinib 200 mg capsule, 60

10323H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	7280.42	40.30	Xalkori [PF]

crizotinib 250 mg capsule, 60

10322G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	7280.42	40.30	Xalkori [PF]

■ **CRIZOTINIB**

Note Special Pricing Arrangements apply.

Authority required

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

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

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

- (1) a completed authority prescription form; and
- (2) a completed ROS1-Positive Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form, which includes details of ROS1 gene rearrangement in tumour material.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

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

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

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

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 January 2019, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing prior to initiating non-PBS subsidised treatment with this drug for this condition.

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

- (1) a completed authority prescription form; and
- (2) a completed ROS1-Positive Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form, which includes details of ROS1 gene rearrangement in tumour material.

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

crizotinib 200 mg capsule, 60

11589Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	7280.42	40.30	Xalkori [PF]

crizotinib 250 mg capsule, 60

11594F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	7280.42	40.30	Xalkori [PF]

■ DABRAFENIB

Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive 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.

Authority required (STREAMLINED)

6044

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS subsidised therapy; OR
- Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

dabrafenib 75 mg capsule, 120

2846T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	8333.68	40.30	Tafinlar [NV]

dabrafenib 50 mg capsule, 120

2963Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	5606.50	40.30	Tafinlar [NV]

■ DABRAFENIB

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

Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive 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.

Authority required (STREAMLINED)

6013

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

dabrafenib 75 mg capsule, 120

10003L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8333.68	40.30	Tafinlar [NV]

dabrafenib 50 mg capsule, 120

2954L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5606.50	40.30	Tafinlar [NV]

■ DASATINIB

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesilate is not approved for use in second or third line treatment. Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not

failed prior PBS-subsidised treatment with that agent. Nilotinib is not approved for patients in blast crisis. 1. Initial second line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response. 2. Initial third line treatment Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent. From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis. 3. Continuing treatment for second and third line treatment All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows: (i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained. During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent. 4. Authority approval requirements. Response criteria to initial treatment with dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent). 5. Definitions of response. A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response. 6. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have failed PBS-subsidised first line treatment with this drug for this condition, **AND**
 - Patient must have failed an adequate trial of PBS-subsidised first line treatment with imatinib for this condition; OR
 - Patient must have failed an adequate trial of PBS-subsidised first line treatment with nilotinib for this condition; OR
 - Patient must have experienced intolerance, not a failure of response, to PBS-subsidised second line treatment with nilotinib for this condition, **AND**
 - The treatment must be the sole PBS-subsidised therapy for this condition.
- Failure of an adequate trial of imatinib or nilotinib is defined as: (i) Lack of response to initial imatinib or nilotinib therapy, defined as either: - failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or - failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or - failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR (ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR (iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR (iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following: (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or (3) Peripheral basophils greater than or equal to 20%; or (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR Blast crisis is defined as either: (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or (2) Extramedullary involvement other than spleen and liver; OR (v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils

or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia. Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and (c) a signed patient acknowledgement; and (d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and (e) where there has been a loss of response to imatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received initial PBS- subsidised second line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second line treatment with nilotinib for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response in the preceding 18 months and thereafter at 12 monthly intervals; OR
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and (3) demonstration of continued response to treatment as evidenced by either: (a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report need be provided; or (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report need be provided.

dasatinib 70 mg tablet, 60

2485T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5246.17	40.30	Sprycel [BQ]

dasatinib 100 mg tablet, 30

9342Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4266.64	40.30	Sprycel [BQ]

dasatinib 20 mg tablet, 60

2478K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2650.17	40.30	Sprycel [BQ]

dasatinib 50 mg tablet, 60

2482P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4266.64	40.30	Sprycel [BQ]

■ DASATINIB

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

For imatinib mesilate:

First continuing applications may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

For dasatinib or nilotinib:

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements. Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be a primary diagnosis, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form; and
- (3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First continuing treatment

Clinical criteria:

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised first line treatment with this drug for this condition; OR

- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
 - Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
 - Patient must have demonstrated a major cytogenetic response; OR
 - Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**
 - The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
 - The treatment must be the sole PBS-subsidised therapy for this condition.
- First continuing applications for authorisation must be in writing and must include:
- (1) a completed authority prescription form; and
 - (2) demonstration of continued response to treatment as evidenced by either:
 - (a) a major cytogenetic response [see Note explaining requirements]; or
 - (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

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

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- The condition must be in the chronic phase, **AND**
- Patient must have received the First continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenetic response; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

dasatinib 70 mg tablet, 60

1415L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5246.17	40.30	Sprycel [BQ]

dasatinib 100 mg tablet, 30

1416M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4266.64	40.30	Sprycel [BQ]

dasatinib 20 mg tablet, 60

1354G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2650.17	40.30	Sprycel [BQ]

dasatinib 50 mg tablet, 60

1381Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4266.64	40.30	Sprycel [BQ]

■ DASATINIB

Note No applications for increased repeats will be authorised.

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**

- Patient must have failed treatment with chemotherapy, **AND**
- Patient must have failed treatment with imatinib, **AND**
- Patient must have failed an allogeneic haemopoietic stem cell transplantation if applicable, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of treatment is defined as either:

- (i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;
 - (ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;
 - (iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.
- Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

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

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

Note Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy following treatment with imatinib, **AND**
- The condition must not have progressed, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Note Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

Note Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition.

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

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at www.humanservices.gov.au
 Applications for authority to prescribe should be forwarded to:
 Department of Human Services
 Complex Drugs
 Reply Paid 9826
 HOBART TAS 7001

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required

Acute lymphoblastic leukaemia
 Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
 - Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with imatinib as a first-line therapy for this condition, **AND**
 - The condition must be expressing the Philadelphia chromosome; OR
 - The condition must have the transcript BCR-ABL, **AND**
 - The treatment must be for maintenance of first complete remission, **AND**
 - The treatment must be in combination with chemotherapy or corticosteroids.
- Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

Note Any queries concerning the arrangements to prescribe this drug beyond 24 months 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).

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

dasatinib 70 mg tablet, 60

9127J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	5246.17	40.30	Sprycel [BQ]

dasatinib 100 mg tablet, 30

9343R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4266.64	40.30	Sprycel [BQ]

dasatinib 20 mg tablet, 60

9125G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2650.17	40.30	Sprycel [BQ]

dasatinib 50 mg tablet, 60

9126H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4266.64	40.30	Sprycel [BQ]

▪ **ERLOTINIB**

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
 Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

erlotinib 25 mg tablet, 30

10022L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	262.41	40.30	Tarceva [RO]

erlotinib 150 mg tablet, 30

10014C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1151.77	40.30	Tarceva [RO]

erlotinib 100 mg tablet, 30

10020J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	938.78	40.30	Tarceva [RO]

■ ERLOTINIB**Authority required (STREAMLINED)****4600**

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

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, **AND**
- Patient must not have progressive disease.

Population criteria:

- Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR
- Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

erlotinib 25 mg tablet, 30

10028T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	262.41	40.30	Tarceva [RO]

erlotinib 150 mg tablet, 30

10025P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1151.77	40.30	Tarceva [RO]

erlotinib 100 mg tablet, 30

10019H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	938.78	40.30	Tarceva [RO]

■ ERLOTINIB**Authority required (STREAMLINED)****7446**

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

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

Population criteria:

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

erlotinib 25 mg tablet, 30

11263T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	262.41	40.30	Tarceva [RO]

erlotinib 150 mg tablet, 30

11259N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1151.77	40.30	Tarceva [RO]

erlotinib 100 mg tablet, 30

11260P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	938.78	40.30	Tarceva [RO]

■ EVEROLIMUS**Authority required (STREAMLINED)****7431**

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated a response to prior treatment.

everolimus 10 mg tablet, 30

11267B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1726.74	40.30	Afinitor [NV]

everolimus 5 mg tablet, 30

11254H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	891.77	40.30	Afinitor [NV]

everolimus 2.5 mg tablet, 30

11258M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	448.48	40.30	Afinitor [NV]

▪ **EVEROLIMUS****Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

everolimus 2.5 mg tablet, 30

2818H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	448.48	40.30	Afinitor [NV]

▪ **EVEROLIMUS****Note** No increase in the maximum number of repeats may be authorised.**Authority required**

Refractory seizures associated with tuberous sclerosis complex

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed diagnosis of tuberous sclerosis complex (TSC), **AND**
- Patient must be experiencing a minimum of two partial-onset seizures per week, **AND**
- The condition must have failed to be controlled satisfactorily at stable doses of at least two anti-epileptic drugs, **AND**
- The treatment must be in combination with at least one anti-epileptic drug, **AND**
- Patient must not be a candidate for curative surgery.

Population criteria:

- Patient must be at least 2 years of age.

everolimus 5 mg dispersible tablet, 30

11592D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	891.55	40.30	Afinitor [NV]

everolimus 3 mg dispersible tablet, 30

11599L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	537.00	40.30	Afinitor [NV]

everolimus 2 mg dispersible tablet, 30

11591C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	359.73	40.30	Afinitor [NV]

▪ **EVEROLIMUS****Note** No increase in the maximum number of repeats may be authorised.**Authority required (STREAMLINED)****8262**

Refractory seizures associated with tuberous sclerosis complex

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have maintained a response to the PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with at least one anti-epileptic drug, **AND**
- Patient must not be a candidate for curative surgery.

everolimus 5 mg dispersible tablet, 30

11598K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	891.55	40.30	Afinitor [NV]

everolimus 3 mg dispersible tablet, 30

11608Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	537.00	40.30	Afinitor [NV]

everolimus 2 mg dispersible tablet, 30

11607X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	359.73	40.30	Afinitor [NV]

■ 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.

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.

everolimus 10 mg tablet, 30

10135K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1726.74	40.30	^a Afinitor [NV]	^a Everolimus Sandoz [SZ]

everolimus 5 mg tablet, 30

10131F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	891.77	40.30	^a Afinitor [NV]	^a Everolimus Sandoz [SZ]

■ 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.

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.

everolimus 10 mg tablet, 30

11377T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1726.74	40.30	^a Afinitor [NV]	^a Everolimus Sandoz [SZ]

everolimus 5 mg tablet, 30

11362B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	891.77	40.30	^a Afinitor [NV]	^a Everolimus Sandoz [SZ]

■ EVEROLIMUS**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

Authority required

Metastatic (Stage IV) breast cancer

Clinical criteria:

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole, **AND**
- The treatment must be in combination with exemestane.

Population criteria:

- Patient must not be pre-menopausal.

Note Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

everolimus 10 mg tablet, 30

2985D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1726.74	40.30	Afinitor [NV]

everolimus 5 mg tablet, 30

2819J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	891.77	40.30	Afinitor [NV]

■ 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 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.

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 prior 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 everolimus.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

everolimus 10 mg tablet, 30

10132G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1726.74	40.30	Afinitor [NV]

everolimus 5 mg tablet, 30

10133H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	891.77	40.30	Afinitor [NV]

■ 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.

Authority required (STREAMLINED)

7432

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial 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.

everolimus 10 mg tablet, 30

11262R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1726.74	40.30	Afinitor [NV]

everolimus 5 mg tablet, 30

11257L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	891.77	40.30	Afinitor [NV]

■ GEFITINIB
Authority required (STREAMLINED)
7447

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

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

gefitinib 250 mg tablet, 30

11264W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1271.13	40.30	Iressa [AP]

■ GEFITINIB
Authority required

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

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

gefitinib 250 mg tablet, 30

8769M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1271.13	40.30	Iressa [AP]

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be considered unsuitable for treatment or retreatment with a purine analogue.

A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:

- Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;
- Age is 70 years or older;
- Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;
- History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;

e) Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH).

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

ibrutinib 140 mg capsule, 90

11213E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8785.41	40.30	Imbruvica [JC]

■ **IBRUTINIB**

Note Special Pricing Arrangements apply.

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

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

Authority required

Mantle cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Authority required

Mantle cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Authority required

Mantle cell lymphoma

Treatment Phase: Grandfather treatment

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2018, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

ibrutinib 140 mg capsule, 120

11419B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	11663.17	40.30	Imbruvica [JC]

■ **IMATINIB**

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required (STREAMLINED)

9278

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

imatinib 400 mg tablet, 30

11788K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	Glivec [AF]

imatinib 100 mg tablet, 60

11784F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	952.47	40.30	Glivec [AF]

■ **IMATINIB**

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

Authority required

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records.

imatinib 400 mg tablet, 30

5444M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	Glivec [AF]

imatinib 100 mg tablet, 60

5443L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	952.47	40.30	Glivec [AF]

■ **IMATINIB**

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10918P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

9176Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ **IMATINIB**

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFR fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.

The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10921T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 400 mg tablet, 30

9179D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a Glivec [AF]	^a IMATINIB RBX [RA]

■ **IMATINIB**

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
 - The treatment must not exceed a maximum dose of 400 mg per day.
- A pathology report confirming the presence of the FIP1L1-PDGFR fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10925B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 400 mg tablet, 30

9175X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ **IMATINIB**

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10933K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 400 mg tablet, 30

9173T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ **IMATINIB**

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10939R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 400 mg tablet, 30

9177B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ **IMATINIB**

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFR fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.

The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10940T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

9178C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a Glivec [AF]	^a IMATINIB RBX [RA]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFR fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10941W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

9174W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10942X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

9172R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)**9209**

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**

- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
 - The treatment must not exceed a maximum dose of 800 mg per day.
- Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

11776T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

11753N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)**9243**

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

11756R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)**9243**

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

11757T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

11769K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)**9296**

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

11763D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 400 mg tablet, 30

11758W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)**9206**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

11777W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

11762C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a Glivec [AF]	^a IMATINIB RBX [RA]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)**9209**

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

11764E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 400 mg tablet, 30

11786H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)**9243**

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 400 mg tablet, 30

11765F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)**9296**

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

11770L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

11781C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Authority required (STREAMLINED)**9208**

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

imatinib 400 mg tablet, 30

11778X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1839.66	40.30	Glivec [AF]

imatinib 100 mg tablet, 60

11787J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	952.47	40.30	Glivec [AF]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)**9206**

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

11779Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivarin [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 400 mg tablet, 30

11785G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a Glivec [AF]	^a IMATINIB RBX [RA]

■ IMATINIB

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).

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

Authority required

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records. Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

imatinib 400 mg tablet, 30

9112N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1839.66	40.30	Glivec [AF]

imatinib 100 mg tablet, 60

9111M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	952.47	40.30	Glivec [AF]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

For imatinib mesilate:

First continuing applications may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

For dasatinib or nilotinib:

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements. Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required (STREAMLINED)

9295

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing

Clinical criteria:

- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenetic response; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

imatinib 400 mg capsule, 30

11772N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 400 mg tablet, 30

11752M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

For imatinib mesilate:

First continuing applications may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

For dasatinib or nilotinib:

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements. Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required (STREAMLINED)

9295

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing

Clinical criteria:

- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenetic response; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

imatinib 100 mg capsule, 60

11782D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

11775R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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).

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

For imatinib mesilate:

First continuing applications may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

For dasatinib or nilotinib:

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements. Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation

(FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First Continuing

Clinical criteria:

- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response; OR
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10915L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivaneb [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

9113P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	952.47	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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).

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

For imatinib mesilate:

First continuing applications may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

For dasatinib or nilotinib:

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements. Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First Continuing

Clinical criteria:

- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenic response; OR
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10916M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 400 mg tablet, 30

9114Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1839.66	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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).

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

10917N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 400 mg tablet, 30

9124F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1839.66	40.30	^a Gilmat [CR]	^a Glivec [AF]

^a IMATINIB RBX [RA]

^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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).

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

10924Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

9123E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	952.47	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required (STREAMLINED)

9207

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

imatinib 400 mg capsule, 30

11771M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 400 mg tablet, 30

11789L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1839.66	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required (STREAMLINED)**9207**

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

imatinib 100 mg capsule, 60

11783E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

11780B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	952.47	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note No applications for increased repeats will be authorised.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
- (c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
2. Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
- (c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

imatinib 100 mg capsule, 60

10920R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	952.47	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 100 mg tablet, 60

9115R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	952.47	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note No applications for increased repeats will be authorised.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
- (c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
2. Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
- (c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

imatinib 400 mg capsule, 30

10935M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1839.66	40.30	^a CIPLA IMATINIB ADULT [LR] ^a IMATINIB AN [JO] ^a IMATINIB-DRLA [RZ]	^a Glivanib [JU] ^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]

imatinib 400 mg tablet, 30

9116T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1839.66	40.30	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ LAPATINIB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

Authority required (STREAMLINED)
7441

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

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

The treatment must not exceed a lifetime total of one continuous course.

lapatinib 250 mg tablet, 70

11251E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*2923.27	40.30	Tykerb [NV]

■ LAPATINIB
Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must have received prior therapy with a taxane for at least 3 cycles; OR
- Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must have progressed following treatment with pertuzumab and trastuzumab in combination, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the person has Stage IV disease;

(ii) date of last treatment with a taxane and total number of cycles;

(iii) a copy of the signed patient acknowledgement form;

(iv) dates of treatment with trastuzumab and pertuzumab; and

(v) date of demonstration of progression whilst on treatment with trastuzumab and pertuzumab.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

lapatinib 250 mg tablet, 70

9148L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*2923.27	40.30	Tykerb [NV]

■ LENVATINIB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6604

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be refractory to radioactive iodine, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have symptomatic progressive disease prior to treatment; OR
- Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures, **AND**
- Patient must have thyroid stimulating hormone adequately repressed, **AND**
- Patient must be one in whom surgery is inappropriate, **AND**
- Patient must not be a candidate for radiotherapy with curative intent, **AND**
- Patient must have a WHO performance status of 2 or less.

Radioactive iodine refractory is defined as:

- a lesion without iodine uptake on a radioactive iodine (RAI) scan; or
- having received a cumulative RAI dose of greater than or equal to 600 mCi; or
- progression within 12 months of a single RAI treatment; or
- progression after two RAI treatments administered within 12 months of each other.

Authority required (STREAMLINED)

6578

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be refractory to radioactive iodine, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).

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.

lenvatinib 10 mg capsule, 30

10965D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6462.13	40.30	Lenvima [EI]

lenvatinib 4 mg capsule, 30

10952K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3260.49	40.30	Lenvima [EI]

■ LENVATINIB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

8593

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be suitable for transarterial chemoembolisation, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A, **AND**
- Patient must not have received prior treatment with a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) for this condition; OR
- Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.

Authority required (STREAMLINED)

8618

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment - grandfathered patients

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 March 2019, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be suitable for transarterial chemoembolisation, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A.

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

Authority required (STREAMLINED)**8584**

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition.

lenvatinib 4 mg capsule, 30

11638M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	2	..	*9617.11	40.30	Lenvima [EI]

■ Nilotinib**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be a primary diagnosis, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved. Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form; and (3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and (4) a signed patient acknowledgement form. The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure to respond 2. Continuing First-line treatment -

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate,

dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

3. Authority approval requirements. Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesilate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

4. Definitions of response. A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

5. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First continuing treatment

Clinical criteria:

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response; OR
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) demonstration of continued response to treatment as evidenced by either: (a) a major cytogenetic response [see Note explaining requirements]; or (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- The condition must be in the chronic phase, **AND**
- Patient must have received the First continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenetic response; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Subsequent authority applications for continuing therapy with this drug may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

nilotinib 150 mg capsule, 120

1309X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3847.01	40.30	Tasigna [NV]

■ **NILOTINIB**

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

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

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be in the chronic phase; OR
- The condition must be in the accelerated phase, **AND**
- Patient must have failed an adequate trial of PBS-subsidised first line treatment with imatinib for this condition; OR
- Patient must have failed an adequate trial of PBS-subsidised first line treatment with dasatinib for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or dasatinib is defined as:(i) Lack of response to initial imatinib or dasatinib therapy, defined as either:- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or(3) Peripheral basophils greater than or equal to 20%; or(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:(a) a completed authority prescription form; and(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and(c) a signed patient acknowledgement; and(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and(e) where there has been a loss of response to imatinib or dasatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesilate is not approved for use in second or third line treatment. Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent. Nilotinib is not approved for patients in blast crisis.1. Initial second line treatmentFrom 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy. During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.2. Initial third line treatmentThird-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent. From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.3. Continuing treatment for second and third line treatmentAll continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic

response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained. During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent. 4. Authority approval requirements. Response criteria to initial treatment with dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent). 5. Definitions of response. A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response. 6. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals; **OR**
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and (3) demonstration of continued response to treatment as evidenced by either: (a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided

nilotinib 200 mg capsule, 120

9171Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5047.66	40.30	Tasigna [NV]

■ NINTEDANIB

Note No 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

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

Clinical criteria:

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition.

Treatment criteria:

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must not have an acute respiratory infection at the time of FVC testing.

Application for authorisation of initial treatment must be in writing and must include:

- a) a completed authority prescription form; and
- b) a completed IPF Authority Application Supporting Information Form; and
- c) a signed patient acknowledgement.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or re-commencement of treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition.

Treatment criteria:

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

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

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition.

Treatment criteria:

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

nintedanib 100 mg capsule, 60

11100F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1753.03	40.30	Ofev [BY]

nintedanib 150 mg capsule, 60

11106M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3389.72	40.30	Ofev [BY]

■ OSIMERTINIB

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

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

Note Special Pricing Arrangements apply.

Authority required

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

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Authority required

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

Treatment Phase: Grandfather treatment

Clinical criteria:

- Patient must have received non-PBS subsidised therapy with this drug for this condition prior to 1 February 2019, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised treatment, **AND**
- The condition must have progressed on or after epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy as first line treatment for this condition prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have evidence of EGFR T790M mutation following progression on first line EGFR TKI treatment, **AND**

- Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition.

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

Authority applications for initial treatment must be made in writing and must include:

- a completed authority prescription form;
 - a completed EGFR T790M mutation positive non-small cell lung cancer initial PBS authority application - supporting information form;
 - copy of the pathology report from an Approved Pathology Authority confirming evidence of EGFR T790M mutation in tumour material while on or after first line EGFR TKI treatment; and
 - date of commencement of first line EGFR TKI treatment and date of progression whilst on first line EGFR TKI treatment.
- For patients commencing non-PBS-subsidised treatment between 1 June 2018 and 1 February 2019, evidence of EGFR T790M mutation must be from tumour material.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

osimertinib 40 mg tablet, 30

11620N	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7962.12	40.30	Tagrisso [AP]

■ OSIMERTINIB

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

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

Note Special Pricing Arrangements apply.

Authority required

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

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The condition must have progressed on or after prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy as first line treatment for this condition, **AND**
- Patient must have evidence of EGFR T790M mutation in tumour material at the point of progression on or after first line EGFR TKI treatment.

Authority applications for initial treatment must be made in writing and must include:

- a completed authority prescription form;
- a completed EGFR T790M mutation positive non-small cell lung cancer initial PBS authority application - supporting information form;
- copy of the pathology report from an Approved Pathology Authority confirming evidence of EGFR T790M mutation in tumour material while on or after first line EGFR TKI treatment; and
- date of commencement of first line EGFR TKI treatment and date of progression whilst on first line EGFR TKI treatment.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

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

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Authority required

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

Treatment Phase: Grandfather treatment

Clinical criteria:

- Patient must have received non-PBS subsidised therapy with this drug for this condition prior to 1 February 2019, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised treatment, **AND**
- The condition must have progressed on or after epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy as first line treatment for this condition prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have evidence of EGFR T790M mutation following progression on first line EGFR TKI treatment, **AND**
- Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition.

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

Authority applications for initial treatment must be made in writing and must include:

- a completed authority prescription form;
- a completed EGFR T790M mutation positive non-small cell lung cancer initial PBS authority application - supporting information form;
- copy of the pathology report from an Approved Pathology Authority confirming evidence of EGFR T790M mutation in tumour material while on or after first line EGFR TKI treatment; and
- date of commencement of first line EGFR TKI treatment and date of progression whilst on first line EGFR TKI treatment.

For patients commencing non-PBS-subsidised treatment between 1 June 2018 and 1 February 2019, evidence of EGFR T790M mutation must be from tumour material.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

osimertinib 80 mg tablet, 30

11622Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7962.12	40.30	Tagrisso [AP]

■ PALBOCICLIB

Note No 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

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer, **AND**
- Patient must not have previously been treated with ribociclib; OR
- Patient must have developed an intolerance to ribociclib of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with ribociclib.

Population criteria:

- Patient must not be premenopausal.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with 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 in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with ribociclib.

Population criteria:

- Patient must not be premenopausal.

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

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 May 2019, **AND**
- Patient must not have previously been treated with an aromatase inhibitor prior to initiating treatment with this drug for this condition, **AND**
- Patient must not have previously been treated with ribociclib; OR
- Patient must have developed an intolerance to ribociclib of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less prior to initiating treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with 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 in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with ribociclib.

Population criteria:

- Patient must not be premenopausal.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

palbociclib 75 mg capsule, 21

11699R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4239.97	40.30	Ibrance [PF]

palbociclib 100 mg capsule, 21

11700T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4239.97	40.30	Ibrance [PF]

palbociclib 125 mg capsule, 21

11698Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4239.97	40.30	Ibrance [PF]

■ PAZOPANIB

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 Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7422

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial 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**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor 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.

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

pazopanib 400 mg tablet, 30

2201W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2302.58	40.30	Votrient [NV]

pazopanib 200 mg tablet, 30

2232L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1190.43	40.30	Votrient [NV]

■ PAZOPANIB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**9247**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline, **AND**
- Patient must not have received prior treatment with an angiogenesis inhibitor, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patient must not have any of the following conditions:

adipocytic soft tissue sarcoma;

gastrointestinal stromal tumour (GIST);

rhabdomyosarcoma other than alveolar or pleomorphic;

chondrosarcoma;

osteosarcoma;

Ewings tumour/primitive neuroectodermal tumour;

dermofibromatosis sarcoma protuberans;

inflammatory myofibroblastic sarcoma;

malignant mesothelioma;

mixed mesodermal tumour of the uterus.

pazopanib 200 mg tablet, 90

10042M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3377.81	40.30	Votrient [NV]

pazopanib 400 mg tablet, 60

10041L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4453.04	40.30	Votrient [NV]

■ PAZOPANIB

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 (STREAMLINED)**7458**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial 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.

pazopanib 200 mg tablet, 90

10047T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3377.81	40.30	Votrient [NV]

pazopanib 400 mg tablet, 60

10043N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4453.04	40.30	Votrient [NV]

■ PAZOPANIB

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 (STREAMLINED)

7459

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial 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**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

pazopanib 400 mg tablet, 30

10052C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2302.58	40.30	Votrient [NV]

pazopanib 200 mg tablet, 30

10054E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1190.43	40.30	Votrient [NV]

■ **PAZOPANIB**

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 (STREAMLINED)

7423

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial 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 tyrosine kinase inhibitor 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.

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

pazopanib 200 mg tablet, 90

11252F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3377.81	40.30	Votrient [NV]

pazopanib 400 mg tablet, 60

11261Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4453.04	40.30	Votrient [NV]

■ **PAZOPANIB**

Note No 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 Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.

Note Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

Authority required (STREAMLINED)

9281

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
 - Patient must have a WHO performance status of 2 or less, **AND**
 - The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.
- Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

pazopanib 200 mg tablet, 90

2029T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3377.81	40.30	Votrient [NV]

pazopanib 400 mg tablet, 60

2030W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4453.04	40.30	Votrient [NV]

■ PONATINIB

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation, **AND**
- Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor, **AND**
- Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).

Failure of treatment is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor;
 2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor;
 3. Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.
- Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

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

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS authority application form; and
3. a signed patient acknowledgement; and
4. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript.; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have progressive disease.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

ponatinib 15 mg tablet, 60

10523W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	5760.73	40.30	Iclusig [TS]

ponatinib 45 mg tablet, 30

10524X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	6480.17	40.30	Iclusig [TS]

■ PONATINIB**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed prior treatment with PBS-subsidised dasatinib for this condition; OR
- Patient must have developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of treatment with ponatinib is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with PBS-subsidised dasatinib for this condition; or
2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by PBS-subsidised dasatinib for this condition; or
3. Rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission; OR rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

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

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia ponatinib PBS Authority Application - Supporting Information Form; and
3. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided; or
4. pathology reports documenting rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition. The date of the relevant pathology report(s) need(s) to be provided

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Grandfather treatment

Clinical criteria:

- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 September 2018, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed prior treatment with PBS-subsidised dasatinib for this condition; OR
- Patient must have developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal, **AND**

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

Failure of treatment with dasatinib is defined as either:

- Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with PBS-subsidised dasatinib for this condition; or
- Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by PBS-subsidised dasatinib for this condition; or
- Rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission; OR rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

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

- a completed authority prescription form; and
- a completed Acute Lymphoblastic Leukaemia ponatinib PBS Authority Application - Supporting Information Form; and
- a pathology report demonstrating that the patient had active acute lymphoblastic leukaemia, manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript at the time treatment with ponatinib was initiated. The date of the relevant pathology report(s) need(s) to be provided; or
- pathology reports documenting rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition. The date of the relevant pathology report(s) need(s) to be provided

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

ponatinib 15 mg tablet, 60

11454W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	5760.73	40.30	Iclusig [TS]

ponatinib 45 mg tablet, 30

11453T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	6480.17	40.30	Iclusig [TS]

■ PONATINIB

Note Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib or ponatinib at any one time and must not be receiving concomitant interferon alfa therapy.

Note 1. Continuing treatment

First continuing applications are to be written, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment. Subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

2. Authority approval requirements.

Response criteria to treatment with ponatinib:

For the purposes of assessing response to PBS-subsidised treatment with ponatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted within 18 months of the commencement of treatment with ponatinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive first continuing treatment with this drug).

Thereafter, at no greater than 12 month intervals a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% must be sustained to receive subsequent continuing treatments with this drug.

3. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006).

4. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing

consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have failed an adequate trial of dasatinib; OR
- Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have failed an adequate trial of nilotinib; OR
- Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal; OR
- Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis.

Failure of an adequate trial of dasatinib or nilotinib is defined as:

1. Lack of response to dasatinib or nilotinib therapy, defined as either:
 - (i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or
 - (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
 - (iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib or nilotinib; OR
2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib or nilotinib therapy; OR
3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib or nilotinib therapy; OR
4. Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR
5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
2. Extramedullary involvement other than spleen and liver.

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

1. a completed authority prescription form; and
2. a completed Chronic Myeloid Leukaemia - ponatinib Initial PBS authority application form; and
3. a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and
4. where there has been a loss of response to dasatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation, **AND**
- Patient must have failed an adequate trial of imatinib; OR
- Patient must have failed an adequate trial of dasatinib; OR

- Patient must have failed an adequate trial of nilotinib.
- Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as:
1. Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either:
 - (i) failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or
 - (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
 - (iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib or nilotinib; OR
 2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib or nilotinib therapy; OR
 3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib or nilotinib therapy; OR
 4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR
 5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
2. Extramedullary involvement other than spleen and liver.

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

1. a completed authority prescription form; and
2. a completed Chronic Myeloid Leukaemia - ponatinib Initial PBS authority application form; and
3. a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale and evidence of the T315I mutation. (The date of the relevant pathology report(s) need to be provided); and
4. where there has been a loss of response to imatinib or dasatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received initial PBS subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response; OR
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%.

First continuing applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Chronic Myeloid Leukaemia Continuing PBS authority application Supporting information form; and
3. demonstration of continued response to treatment as evidenced by either:
 - (a) major cytogenetic response [see Note explaining definitions of response]; or
 - (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response].

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have maintained a major cytogenetic response at 12 month intervals; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1% at 12 month intervals.

ponatinib 15 mg tablet, 60

10520Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5760.73	40.30	Iclusig [TS]

ponatinib 45 mg tablet, 30

10530F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6480.17	40.30	Iclusig [TS]

▪ RIBOCICLIB

Caution QT interval monitoring is required for patients treated 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.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer, **AND**
- Patient must not have previously been treated with palbociclib; OR
- Patient must have developed an intolerance to palbociclib of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with palbociclib, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets.

Population criteria:

- Patient must not be premenopausal.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with palbociclib, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets.

Population criteria:

- Patient must not be premenopausal.

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

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2018, **AND**
- Patient must not have previously been treated with an aromatase inhibitor prior to initiating treatment with this drug for this condition, **AND**
- Patient must not have previously been treated with palbociclib; OR
- Patient must have developed an intolerance to palbociclib of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less prior to initiating treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with palbociclib, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets.

Population criteria:

- Patient must not be premenopausal.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

ribociclib 200 mg tablet, 21

11385F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1926.77	40.30	Kisqali [NV]

■ RIBOCICLIB

Caution QT interval monitoring is required for patients treated 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.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer, **AND**
- Patient must not have previously been treated with palbociclib; OR
- Patient must have developed an intolerance to palbociclib of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with palbociclib.

Population criteria:

- Patient must not be premenopausal.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with palbociclib.

Population criteria:

- Patient must not be premenopausal.

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

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2018, **AND**
- Patient must not have previously been treated with an aromatase inhibitor prior to initiating treatment with this drug for this condition, **AND**
- Patient must not have previously been treated with palbociclib; OR
- Patient must have developed an intolerance to palbociclib of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less prior to initiating treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with palbociclib.

Population criteria:

- Patient must not be premenopausal.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

ribociclib 200 mg tablet, 63

11386G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5512.13	40.30	Kisqali [NV]

■ RIBOCICLIB

Caution QT interval monitoring is required for patients treated 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.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer, **AND**
- Patient must not have previously been treated with palbociclib; OR
- Patient must have developed an intolerance to palbociclib of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with palbociclib, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

Population criteria:

- Patient must not be premenopausal.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with palbociclib, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

Population criteria:

- Patient must not be premenopausal.

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

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2018, **AND**
- Patient must not have previously been treated with an aromatase inhibitor prior to initiating treatment with this drug for this condition, **AND**
- Patient must not have previously been treated with palbociclib; OR
- Patient must have developed an intolerance to palbociclib of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less prior to initiating treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with palbociclib, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

Population criteria:

- Patient must not be premenopausal.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

ribociclib 200 mg tablet, 42

11397W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3725.46	40.30	Kisqali [NV]

▪ **RUXOLITINIB**

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Authority required

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Authority required

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

ruxolitinib 15 mg tablet, 56

10615Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5152.12	40.30	Jakavi [NV]

ruxolitinib 10 mg tablet, 56

10927D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5152.12	40.30	Jakavi [NV]

ruxolitinib 5 mg tablet, 56

10616R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*5152.13	40.30	Jakavi [NV]

ruxolitinib 20 mg tablet, 56

10617T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5152.12	40.30	Jakavi [NV]

RUXOLITINIB

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

Note Written applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Programs

Reply Paid 9826

HOBART TAS 7001

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Authority required

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.

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

- (1) A completed authority prescription form; and
- (2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
 - (a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and
 - (b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

Authority required

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy.

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

- (1) A completed authority prescription form; and
- (2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
 - a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis;
 - b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and
 - c) A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy.

ruxolitinib 15 mg tablet, 56

10619X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	5152.12	40.30	Jakavi [NV]

ruxolitinib 10 mg tablet, 56

10913J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	5152.12	40.30	Jakavi [NV]

ruxolitinib 5 mg tablet, 56

10614P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*5152.13	40.30	Jakavi [NV]

ruxolitinib 20 mg tablet, 56

10618W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	5152.12	40.30	Jakavi [NV]

SORAFENIB

Note No 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 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.

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 prior 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.

sorafenib 200 mg tablet, 60

10226F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*5547.79	40.30	Nexavar [BN]

■ SORAFENIB

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 (STREAMLINED)

7487

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial 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.

sorafenib 200 mg tablet, 60

10242C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*5547.79	40.30	Nexavar [BN]

■ SORAFENIB

Note Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.

Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

8616

Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A, **AND**
- Patient must not have received prior treatment with a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) for this condition; OR
- Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.

Authority required (STREAMLINED)

8617

Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition.

sorafenib 200 mg tablet, 60

9380Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*5547.79	40.30	Nexavar [BN]

■ 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.

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.

sunitinib 12.5 mg capsule, 28

10004M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1737.14	40.30	Sutent [PF]

sunitinib 50 mg capsule, 28

2837H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	6565.65	40.30	Sutent [PF]

sunitinib 25 mg capsule, 28

2959R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3358.75	40.30	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10464R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4962.20	40.30	Sutent [PF]

■ 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.

Authority required (STREAMLINED)

7471

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

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

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

sunitinib 12.5 mg capsule, 28

10009T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1737.14	40.30	Sutent [PF]

sunitinib 50 mg capsule, 28

10010W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6565.65	40.30	Sutent [PF]

sunitinib 25 mg capsule, 28

2842N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3358.75	40.30	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10473F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4962.20	40.30	Sutent [PF]

■ SUNITINIB

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 (STREAMLINED)

7466

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

- Patient must have received an initial 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 tyrosine kinase inhibitor 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.

Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

sunitinib 12.5 mg capsule, 28

9420T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1737.14	40.30	Sutent [PF]

sunitinib 50 mg capsule, 28

9422X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6565.65	40.30	Sutent [PF]

sunitinib 25 mg capsule, 28

9421W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	3358.75	40.30	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10459L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	4962.20	40.30	Sutent [PF]

▪ **SUNITINIB**

Note Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

Note Written applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority required

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
 - Patient must have a WHO performance status of 2 or less, **AND**
 - Patient must have previously failed or be intolerant to imatinib mesilate.
- Applications for authorisation must be in writing and must include:
- (1) a completed authority prescription form; and
 - (2) a completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form; and
 - (3) a signed patient acknowledgement.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

sunitinib 12.5 mg capsule, 28

9488J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1737.14	40.30	Sutent [PF]

sunitinib 50 mg capsule, 28

9490L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	6565.65	40.30	Sutent [PF]

sunitinib 25 mg capsule, 28

9489K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3358.75	40.30	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10503T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4962.20	40.30	Sutent [PF]

■ 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.

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

Note Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

Authority required (STREAMLINED)**9210**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

sunitinib 12.5 mg capsule, 28

9417P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1737.14	40.30	Sutent [PF]

sunitinib 50 mg capsule, 28

9419R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	6565.65	40.30	Sutent [PF]

sunitinib 25 mg capsule, 28

9418Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3358.75	40.30	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10504W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4962.20	40.30	Sutent [PF]

■ SUNITINIB

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

Note Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug

Note Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**7430**

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have progressive disease.

sunitinib 12.5 mg capsule, 28

11266Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1737.14	40.30	Sutent [PF]

sunitinib 50 mg capsule, 28

11250D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	6565.65	40.30	Sutent [PF]

sunitinib 25 mg capsule, 28

11253G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3358.75	40.30	Sutent [PF]

sunitinib 37.5 mg capsule, 28

11256K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4962.20	40.30	Sutent [PF]

■ TRAMETINIB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**6778**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, **AND**
- Patient must not have had progressive disease when treated with a BRAF inhibitor.

trametinib 500 microgram tablet, 30

10403M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*6611.23	40.30	Mekinist [NV]

trametinib 2 mg tablet, 30

10382K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	8764.29	40.30	Mekinist [NV]

■ TRAMETINIB

Note A patient who has progressive disease when treated with this drug is 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.

Authority required (STREAMLINED)**6752**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

trametinib 500 microgram tablet, 30

10385N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*6611.23	40.30	Mekinist [NV]

trametinib 2 mg tablet, 30

10405P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8764.29	40.30	Mekinist [NV]

■ VEMURAFENIB

Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive 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.

Authority required (STREAMLINED)**6044**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS subsidised therapy; OR
- Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

vemurafenib 240 mg tablet, 56

11076Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*8190.19	40.30	Zelboraf [RO]

■ VEMURAFENIB

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

Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive 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.

Authority required (STREAMLINED)

6013

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

vemurafenib 240 mg tablet, 56

11081F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*8190.19	40.30	Zelboraf [RO]

Other antineoplastic agents
■ HYDROXYCARBAMIDE (HYDROXYUREA)
hydroxycarbamide (hydroxyurea) 500 mg capsule, 100

3093T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	63.20	40.30	Hydrea [BQ]

■ IDELALISIB

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 8 doses, followed by monotherapy, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The condition must be CD20 positive, **AND**
- Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage), **AND**
- Patient must be inappropriate for chemo-immunotherapy.

A patient can be considered inappropriate for chemo-immunotherapy when one or more of the following are experienced:

1. Severe neutropenia defined as absolute neutrophil count of less than or equal to $1.0 \times 10^9/L$; or
2. Severe thrombocytopenia defined as platelet count of less than or equal to $50 \times 10^9/L$; or
3. Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH).

Full blood count results must be no more than 1 month old at the time of application.

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

- a) A completed authority prescription form;
- b) A completed CLL/SLL PBS Authority Application - Supporting information form; and
- c) Pathology report indicating that the patient can be considered inappropriate for chemo-immunotherapy due to one or more of the following:
 - 1) Recent severe neutropenia; or
 - 2) Recent severe thrombocytopenia; or
 - 3) Presence of 17p chromosomal deletion using fluorescence in situ hybridisation (FISH).

A Grandfathered patient who has previously received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017 must have met all the initial restriction criteria prior to initiating non-PBS subsidised treatment. A

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

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

idelalisib 150 mg tablet, 60

11162L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5369.87	40.30	Zydelig [GI]

idelalisib 100 mg tablet, 60

11170X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5369.87	40.30	Zydelig [GI]

■ IDELALISIB

Note No 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

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be refractory to a prior therapy with rituximab, **AND**
- The condition must be refractory to a prior therapy with an alkylating agent, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition.

The condition is considered refractory to a prior therapy when the patient experiences less than a partial response or progression of disease within 6 months after completion of the prior therapy.

The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.

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

- A completed authority prescription form; and
- A completed Refractory follicular B-cell non-Hodgkin's lymphoma PBS Authority Application - Supporting information form which must include date of completion of prior therapies with rituximab and an alkylating agent.

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

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

Written applications for authority to prescribe this drug should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

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

idelalisib 150 mg tablet, 60

11165P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5369.87	40.30	Zydelig [GI]

idelalisib 100 mg tablet, 60

11171Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5369.87	40.30	Zydelig [GI]

■ OLAPARIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**6715**

High grade serous ovarian cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have progressive disease.

Authority required (STREAMLINED)**6705**

High grade serous fallopian tube cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have progressive disease.

Authority required (STREAMLINED)**6716**

High grade serous primary peritoneal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have progressive disease.

olaparib 50 mg capsule, 4 x 112

11050N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6962.12	40.30	Lynparza [AP]

■ OLAPARIB

Caution Do not substitute olaparib 50 mg capsules with olaparib 100 mg or 150 mg tablets on a mg to mg basis due to difference in dosing and bioavailability of each formulation.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**8169**

High grade serous ovarian cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Authority required (STREAMLINED)**8171**

High grade serous fallopian tube cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Authority required (STREAMLINED)

8188

High grade serous primary peritoneal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

olaparib 100 mg tablet, 56

11503K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6962.13	40.30	Lynparza [AP]

olaparib 150 mg tablet, 56

11539H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6962.13	40.30	Lynparza [AP]

■ OLAPARIB

Caution Do not substitute olaparib 50 mg capsules with olaparib 100 mg or 150 mg tablets on a mg to mg basis due to difference in dosing and bioavailability of each formulation.

Note Special Pricing Arrangements apply.

Authority required

High grade serous ovarian cancer

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be platinum sensitive, **AND**
 - The condition must be a germline class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
 - Patient must have received at least two previous platinum-containing regimens, **AND**
 - Patient must have relapsed following a previous platinum-containing regimen, **AND**
 - Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
 - The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
 - The treatment must be maintenance therapy, **AND**
 - Patient must not have previously received PBS-subsidised treatment with this drug for this condition.
- Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline testing.

Authority required

High grade serous fallopian tube cancer

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be platinum sensitive, **AND**
 - The condition must be a germline class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
 - Patient must have received at least two previous platinum-containing regimens, **AND**
 - Patient must have relapsed following a previous platinum-containing regimen, **AND**
 - Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
 - The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
 - The treatment must be maintenance therapy, **AND**
 - Patient must not have previously received PBS-subsidised treatment with this drug for this condition.
- Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline testing.

Authority required

High grade serous primary peritoneal cancer

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be platinum sensitive, **AND**
- The condition must be a germline class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- Patient must have received at least two previous platinum-containing regimens, **AND**
- Patient must have relapsed following a previous platinum-containing regimen, **AND**

- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
 - The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
 - The treatment must be maintenance therapy, **AND**
 - Patient must not have previously received PBS-subsidised treatment with this drug for this condition.
- Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline testing.

olaparib 100 mg tablet, 56

11522K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6962.13	40.30	Lynparza [AP]

olaparib 150 mg tablet, 56

11528R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6962.13	40.30	Lynparza [AP]

■ SONIDEGB

Caution Sonidegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 20 months and 6 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

Note No 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 locally advanced basal cell carcinoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; **OR**
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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

- A completed authority prescription form; and
- A completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and
- A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and
- A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and
- A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and
- A signed patient acknowledgement.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Inappropriate for surgery is defined as:

i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; **or**

ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); **or**

iii/ Medical contraindication to surgery

Inappropriate for curative radiotherapy is defined as:

i/Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; **or**

ii/ Limitations due to location of tumour; **or**

iii/ Limitations due to cumulative prior radiotherapy dose; **or**

iv/ Progressive disease despite prior irradiation of locally advanced BCC.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic or locally advanced basal cell carcinoma
Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

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

- a) A completed authority prescription form; and
- b) A completed Basal Cell Carcinoma Continuing PBS Authority Application Form - Supporting Information Form; and
- c) A confirmation statement from the treating doctor that the disease has not progressed; and
- d) In patients with locally advanced BCC, a letter from a surgically qualified clinician demonstrating that the condition remains inappropriate for surgery; or a letter from a radiation oncologist demonstrating that the condition remains inappropriate for curative radiotherapy

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Inappropriate for surgery is defined as:

- i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or
- ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or
- iii/ Medical contraindication to surgery

Inappropriate for curative radiotherapy is defined as:

- i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or
- ii/ Limitations due to location of tumour; or
- iii/ Limitations due to cumulative prior radiotherapy dose; or
- iv/ Progressive disease despite prior irradiation of locally advanced BCC

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic or locally advanced basal cell carcinoma
Treatment Phase: Initial treatment or Continuing treatment – balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete 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).

sonidegib 200 mg capsule, 30

11304Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7973.55	40.30	Odomzo [RA]

▪ VENETOCLAX

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Initial treatment - Extension of dose titration

Clinical criteria:

- Patient must have experienced a treatment interruption during the PBS-subsidised dose titration with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be used as monotherapy for this condition under this restriction.

venetoclax 10 mg tablet, 14

11624T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	107.11	40.30	Venclexta [VE]

venetoclax 50 mg tablet, 7

11648C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	252.61	40.30	Venclexta [VE]

▪ **VENETOCLAX**

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Initial treatment - Dose titration

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be considered unsuitable for treatment or retreatment with a purine analogue, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be used as monotherapy for this condition under this restriction.

A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:

- Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;
- Age is 70 years or older;
- Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;
- History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;
- Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH).

venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack

11630D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	1780.45	40.30	Venclexta [VE]

▪ **VENETOCLAX**

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 6 cycles, followed by monotherapy, **AND**
- The treatment must be ceased on disease progression or on completion of 24 months of PBS-subsidised treatment with this drug for this condition, whichever comes first.

Authority required

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Grandfathered treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 March 2019, **AND**

- Patient must have been considered unsuitable for treatment or retreatment with a purine analogue prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 6 cycles, followed by monotherapy, **AND**
- The treatment must be ceased on disease progression or on completion of 24 months of PBS-subsidised treatment with this drug for this condition, whichever comes first.

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

venetoclax 100 mg tablet, 120

11639N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7775.14	40.30	Venclexta [VE]

■ VISMODEGIB

Caution Vismodegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 24 months and 2 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

Note No 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 locally advanced basal cell carcinoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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

- A completed authority prescription form; and
- A completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and
- A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and
- A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and
- A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and
- A signed patient acknowledgement.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Inappropriate for surgery is defined as:

- Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or
- Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or
- Medical contraindication to surgery

Inappropriate for curative radiotherapy is defined as:

- Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or
- Limitations due to location of tumour; or
- Limitations due to cumulative prior radiotherapy dose; or
- Progressive disease despite prior irradiation of locally advanced BCC.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic or locally advanced basal cell carcinoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

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

- A completed authority prescription form; and
- A completed Basal Cell Carcinoma Continuing PBS Authority Application Form - Supporting Information Form; and
- A confirmation statement from the treating doctor that the disease has not progressed; and
- In patients with locally advanced BCC, a letter from a surgically qualified clinician demonstrating that the condition remains inappropriate for surgery; or a letter from a radiation oncologist demonstrating that the condition remains inappropriate for curative radiotherapy

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Inappropriate for surgery is defined as:

- Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or
- Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or
- Medical contraindication to surgery

Inappropriate for curative radiotherapy is defined as:

- Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or
- Limitations due to location of tumour; or
- Limitations due to cumulative prior radiotherapy dose; or
- Progressive disease despite prior irradiation of locally advanced BCC

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic or locally advanced basal cell carcinoma

Treatment Phase: Initial treatment or Continuing treatment – balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete 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).

vismodegib 150 mg capsule, 28

11070P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7452.12	40.30	Erivedge [RO]

▪ **VORINOSTAT**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No 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

Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received systemic treatment with chemotherapy, **AND**
- Patient must demonstrate relapsed or chemotherapy-refractory disease, **AND**
- Patient must be ineligible for stem cell transplant, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed cutaneous T-cell lymphoma (CTCL) initial PBS Authority Application - Supporting Information Form.

vorinostat 100 mg capsule, 120

11138F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4454.24	40.30	Zolinza [MK]

▪ **VORINOSTAT**

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No 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

Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

vorinostat 100 mg capsule, 120

11141J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4454.24	40.30	Zolinza [MK]

▪ **ENDOCRINE THERAPY**

HORMONES AND RELATED AGENTS

Progestogens

▪ **MEDROXYPROGESTERONE**

Restricted benefit

Advanced breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

medroxyprogesterone acetate 500 mg tablet, 30

2728N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	136.59	40.30	Provera [PF]

▪ **MEDROXYPROGESTERONE**

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

Restricted benefit

Endometrial cancer

medroxyprogesterone acetate 250 mg tablet, 60

2727M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	136.59	40.30	Provera [PF]

medroxyprogesterone acetate 200 mg tablet, 60

2316X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	111.17	40.30	Provera [PF]

medroxyprogesterone acetate 100 mg tablet, 100

2725K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	99.11	40.30	Provera [PF]

Gonadotropin releasing hormone analogues**■ GOSERELIN****Restricted benefit**

Carcinoma of the prostate

Clinical criteria:

- The condition must be locally advanced (stage C); OR
- The condition must be metastatic (stage D).

goserelin 10.8 mg implant, 1

8093Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	900.04	40.30	Zoladex 10.8 Implant [AP]

■ GOSERELIN**Restricted benefit**

Carcinoma of the prostate

Clinical criteria:

- The condition must be locally advanced (stage C); OR
- The condition must be metastatic (stage D).

Restricted benefit

Endometriosis

Clinical criteria:

- The condition must be visually proven, **AND**
- The treatment must be for the short-term (up to 6 months).

Note Only 1 course of not more than 6 months' therapy will be authorised.**Restricted benefit**

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

Restricted benefit

Anticipated premature ovarian failure

Clinical criteria:

- Patient must be receiving treatment with an alkylating agent for a malignancy or an autoimmune disorder that has a high risk of causing premature ovarian failure, **AND**
- Patient must not receive more than 6 months' of treatment for this condition in a lifetime.

Population criteria:

- Patient must be pre-menopausal.

goserelin 3.6 mg implant, 1

1454M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	264.60	40.30	Zoladex Implant [AP]

■ GOSERELIN (&) BICALUTAMIDE**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Restricted benefit**

Carcinoma of the prostate

Clinical criteria:

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack

9065D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	1048.71	40.30	ZolaCos CP 10.8/50(28) [AP]

goserelin 3.6 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack

9064C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	413.91	40.30	ZolaCos CP 3.6/50 [AP]

goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84 tablets], 1 pack

9066E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	1326.44	40.30	ZolaCos CP 10.8/50(84) [AP]

LEUPRORELIN

Restricted benefit

Central precocious puberty

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR
- Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.

Clinical criteria:

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

leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

10255R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1186.76	40.30	Lucrin Depot Paediatric 30 mg PDS [VE]

LEUPRORELIN

Restricted benefit

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

leuprorelin acetate 45 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack

10656W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1740.11	40.30	Lucrin Depot 6-Month [VE]

leuprorelin acetate 45 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack

8859G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1740.11	40.30	Eligard 6 month [MF]

leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8707G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	337.90	40.30	Eligard 1 month [MF]

leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8709J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1186.76	40.30	Eligard 4 month [MF]

leuprorelin acetate 22.5 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack

8876E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	900.04	40.30	Lucrin Depot 3 Month PDS [VE]

leuprorelin acetate 7.5 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack

8875D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	337.90	40.30	Lucrin Depot 7.5mg PDS [VE]

leuprorelin acetate 30 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack

8877F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1186.76	40.30	Lucrin Depot 4 Month PDS [VE]

leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8708H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	900.04	40.30	Eligard 3 month [MF]

LEUPRORELIN

Restricted benefit

Central precocious puberty

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

Population criteria:

- Patient must be aged 10 years or younger (girls) or 11 years or younger (boys), **AND**
- Patient must have had onset of signs or symptoms of central precocious puberty prior to the age of 8 years (girls) or 9 years (boys).

Restricted benefit

Central precocious puberty

Treatment Phase: Initial - grandfather

Clinical criteria:

- Patient must have received treatment with a gonadotropin releasing hormone analogue (GnRHa) for this condition prior to 1 May 2015.

Treatment criteria:

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

leuporelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

10256T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1186.76	40.30	Lucrin Depot Paediatric 30 mg PDS [VE]

LEUPRORELIN (&) INERT SUBSTANCE (&) BICALUTAMIDE

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

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

Restricted benefit

Carcinoma of the prostate

Clinical criteria:

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

leuporelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack

10962Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	416.16	40.30	Bi ELIGARD CP [MF]

leuporelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack

10963B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	978.30	40.30	Bi ELIGARD CP [MF]

leuporelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [84], 1 pack

10969H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	1128.19	40.30	Bi ELIGARD CP [MF]

TRIPTORELIN
Restricted benefit

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

triptorelin 22.5 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

5297T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1827.62	40.30	Diphereline [IS]

triptorelin 11.25 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

9379P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	947.13	40.30	Diphereline [IS]

triptorelin 3.75 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

9378N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	355.42	40.30	Diphereline [IS]

HORMONE ANTAGONISTS AND RELATED AGENTS
Anti-estrogens
TAMOXIFEN

Note This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

Note Shared Care Model:

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

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

tamoxifen 10 mg tablet, 60

2109B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	20.44	21.69	Genox 10 [AF]

TAMOXIFEN

Note For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

Note Shared Care Model:

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

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

tamoxifen 20 mg tablet, 30

1880Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*27.01	28.26	^a Nolvadex-D [AP]

TAMOXIFEN

Note This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

Note For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

Note Shared Care Model:

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

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

tamoxifen 20 mg tablet, 60

2110C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	27.01	28.26	^a Genox 20 [AF] ^a Tamosin [QA]	^a GenRx Tamoxifen [GX] ^a Tamoxifen Sandoz [SZ]

TAMOXIFEN

Note A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

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

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

Restricted benefit

Reduction of breast cancer risk

Clinical criteria:

- Patient must have a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.

tamoxifen 20 mg tablet, 30

10911G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.24	20.49	^a Genox 20 [AF]	^a Nolvadex-D [AP]

TOREMIFENE

toremifene 60 mg tablet, 30

8216K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	61.19	40.30	Fareston [AS]

Anti-androgens

BICALUTAMIDE

Note No 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 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.

Authority required (STREAMLINED)

5729

Metastatic (stage D) carcinoma of the prostate

Clinical criteria:

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

bicalutamide 50 mg tablet, 28

8094B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	57.28	40.30	^a APO-Bicalutamide [TX] ^a Bicalox [ER] ^a Calutex [QA] ^a Cosudex [AP]	^a Bicalide [JU] ^a Bicalutamide AN [JO] ^a Cosamide 50 [AF]

■ CYPROTERONE**cyproterone acetate 50 mg tablet, 50**

1270W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*83.09	40.30	^a ANTERONE 50 [RW] ^a Cyprocur 50 [QA] ^a Cyprostat [SY] ^a Cyproterone Sandoz [HX] ^a Pharmacor Cyproterone 50 [CR]	^a APO-Cyproterone [TX] ^a Cyprone 50 [AL] ^a Cyproterone AN [EA] ^a GenRx Cyproterone Acetate [GX]
			^B 2.28	*85.37	40.30	^a Androcur [BN]	

cyproterone acetate 100 mg tablet, 50

8019C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	67.26	40.30	^a ANTERONE 100 [RW] ^a Cyprocur 100 [QA] ^a Cyprostat-100 [SY] ^a Cyproterone Sandoz [HX] ^a Pharmacor Cyproterone 100 [CR]	^a APO-Cyproterone [TX] ^a Cyprone 100 [AF] ^a Cyproterone AN [EA] ^a GenRx Cyproterone Acetate [GX]
			^B 1.41	68.67	40.30	^a Androcur-100 [BN]	

■ ENZALUTAMIDE**Note** Special Pricing Arrangements apply.**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required**

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have failed treatment with docetaxel due to resistance or intolerance; OR
- Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must not have received prior treatment with abiraterone; OR
- Patient must have developed intolerance to abiraterone of a severity necessitating permanent treatment withdrawal.

enzalutamide 40 mg capsule, 112

10174L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3705.42	40.30	Xtandi [LL]

■ FLUTAMIDE**Note** No 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 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.

Authority required (STREAMLINED)**5816**

Metastatic (stage D) carcinoma of the prostate

Clinical criteria:

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

flutamide 250 mg tablet, 100

1417N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	170.76	40.30	Flutamin [AF]

■ NILUTAMIDE
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.

Authority required (STREAMLINED)
5785

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

Clinical criteria:

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

Authority required (STREAMLINED)
5647

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

Clinical criteria:

- The treatment must be in conjunction with surgical orchidectomy.

nilutamide 150 mg tablet, 30

8131Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	183.79	40.30	Anandron [SW]

Aromatase inhibitors
■ ANASTROZOLE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

Note Shared Care Model:

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

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

anastrozole 1 mg tablet, 30

8179L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.52	30.77	^a Anastrol [QA] ^a Anastrozole FBM [FO] ^a Anastrozole Sandoz [SZ] ^a Arianna 1 [AF] ^a Astzol [JU]	^a Anastrozole AN [JO] ^a Anastrozole GH [GQ] ^a APO-Anastrozole [TX] ^a Arimidex [AP]

■ EXEMESTANE
Restricted benefit

Metastatic (Stage IV) breast cancer

Clinical criteria:

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

Population criteria:

- Patient must not be pre-menopausal.

exemestane 25 mg tablet, 30

10103R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	66.98	40.30	^a APO-Exemestane [TX] ^a Exemestane AN [EA] ^a Exemestane Sandoz [SZ]	^a Estamane [JU] ^a Exemestane GH [GQ]
			^B 4.00	70.98	40.30	^a Aromasin [PF]	

■ EXEMESTANE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

Note Shared Care Model:

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

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

exemestane 25 mg tablet, 30

8506Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	66.98	40.30	^a APO-Exemestane [TX] ^a Exemestane AN [EA] ^a Exemestane Sandoz [SZ]	^a Estamane [JU] ^a Exemestane GH [GQ]
			^B 4.00	70.98	40.30	^a Aromasin [PF]	

■ LETROZOLE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

Note Shared Care Model:

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

Restricted benefit

Breast cancer

Clinical criteria:

- The condition must be hormone receptor positive.

letrozole 2.5 mg tablet, 30

8245Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	31.27	32.52	^a APO-Letrozole [TX] ^a Femolet [AF] ^a Gynotril [ER] ^a Letrozole AN [JO] ^a Letrozole generichealth [GQ] ^a Pharmacor Letrozole 2.5 [CR]	^a Femara 2.5 mg [NV] ^a Fera [QA] ^a Letroz [JU] ^a Letrozole FBM [FO] ^a Letrozole Sandoz [SZ]

*Other hormone antagonists and related agents***■ ABIRATERONE**

Note Special Pricing Arrangements apply.

Authority required

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

- The treatment must be used in combination with a corticosteroid, **AND**
- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have failed treatment with docetaxel due to resistance or intolerance; OR
- Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone, **AND**
- Patient must not have received prior treatment with enzalutamide; OR
- Patient must have developed intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal.

abiraterone acetate 250 mg tablet, 120

2698B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3432.98	40.30	Zytiga [JC]

abiraterone acetate 500 mg tablet, 60

11206T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3432.98	40.30	Zytiga [JC]

■ DEGARELIX**Restricted benefit**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

degarelix 80 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack

2784M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	394.34	40.30	Firmagon 80mg [FP]

■ DEGARELIX

Note No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

Restricted benefit

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

degarelix 120 mg injection [2 vials] (&) inert substance diluent [2 syringes], 1 pack

2785N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	412.54	40.30	Firmagon 120mg [FP]

■ IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Interferons

■ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Myeloproliferative disease

Clinical criteria:

- Patient must have excessive thrombocytosis.

interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

8553E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	4	..	*409.14	40.30	Roferon-A [RO]

■ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Low grade non-Hodgkin's lymphoma

Clinical criteria:

- The condition must have clinical features suggestive of a poor prognosis, **AND**
- The treatment must be in combination with anthracycline-based chemotherapy.

interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

8184R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*409.14	40.30	Roferon-A [RO]

interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

8181N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	15	5	..	*409.24	40.30	Roferon-A [RO]

■ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Hairy cell leukaemia

Authority required

Myeloproliferative disease

Clinical criteria:

- Patient must have excessive thrombocytosis.

interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

8180M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	15	4	..	*409.24	40.30	Roferon-A [RO]

■ INTERFERON BETA-1A

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

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

Authority required (STREAMLINED)

7695

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with 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**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

6860

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

interferon beta-1a 12 million units (44 microgram)/0.5 mL injection, 12 x 0.5 mL pen devices

8968B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	854.85	40.30	Rebif 44 [SG]

interferon beta-1a 12 million units (132 microgram)/1.5 mL injection, 4 x 1.5 mL cartridges

9332E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	854.85	40.30	Rebif 44 [SG]

interferon beta-1a 6 million units (30 microgram)/0.5 mL injection, 4 x 0.5 mL syringes

8805K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	854.85	40.30	Avonex [BD]

interferon beta-1a 12 million units (44 microgram)/0.5 mL injection, 12 x 0.5 mL syringes

8403G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	854.85	40.30	Rebif 44 [SG]

▪ **INTERFERON BETA-1B**

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

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

Authority required (STREAMLINED)

7695

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with 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**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

6860

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack

8101J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	994.78	40.30	Betaferon [BN]

▪ **PEGINTERFERON ALFA-2A**

Note Special Pricing Arrangements apply.

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

11037X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	1272.42	40.30	Pegasys [RO]

peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

11416W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	1109.31	40.30	Pegasys [RO]

■ PEGINTERFERON BETA-1A

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

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

Authority required (STREAMLINED)**7695**

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with 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**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL pen device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL pen device], 1 pack

10218T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	1050.48	40.30	Plegridy [BD]

peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices

10212L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1050.48	40.30	Plegridy [BD]

■ PEGINTERFERON BETA-1A

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

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

Authority required (STREAMLINED)**6860**

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices

10220X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1050.48	40.30	Plegridy [BD]

Other immunostimulants**■ GLATIRAMER ACETATE**

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

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

Authority required (STREAMLINED)**7695**

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with 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**

- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
 - Patient must be ambulatory (without assistance or support).
- Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)**6860**

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes

10416F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	886.03	40.30	Copaxone [TB]

■ MYCOBACTERIUM BOVIS (BACILLUS CALMETTE AND GUERIN (BCG)) TICE STRAIN**Restricted benefit**

Primary and relapsing superficial urothelial carcinoma of the bladder

Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Tice strain 500 million CFU injection, 3 vials

1131M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	449.74	40.30	OncotICE [MK]

■ IMMUNOSUPPRESSANTS**IMMUNOSUPPRESSANTS***Selective immunosuppressants***■ ABATACEPT****Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist. A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months

in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the

baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

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

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

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

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

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

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

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note No 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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

abatacept 125 mg/mL injection, 4 x 1 mL syringes

1221G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	953.62	40.30	Orencia [BQ]

abatacept 125 mg/mL injection, 4 x 1 mL pen devices

11684Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	953.62	40.30	Orencia ClickJect [BQ]

■ ABATACEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
 - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
 - (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
 - (iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
- Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that

biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of

more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

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

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

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

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight

with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

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

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

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

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

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the

date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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

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

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note No 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

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

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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

abatacept 125 mg/mL injection, 4 x 1 mL syringes

1220F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	953.62	40.30	Orencia [BQ]

abatacept 125 mg/mL injection, 4 x 1 mL pen devices

11693K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	953.62	40.30	Orencia ClickJect [BQ]

■ BARICITINIB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a

treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF- α antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months). Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialed and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Grandfathered patients

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 September 2018, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

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

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

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

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

All applications for treatment with this drug for this condition under this restriction must include baseline joint count and ESR and/or CRP as determined at the completion of a 6 month intensive DMARD trial but prior to ceasing DMARD therapy, and measurement of response to the prior course of non-PBS-subsidised therapy with this drug. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

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

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

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

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

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

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

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

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

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

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

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

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing and Initial Grandfathered patients treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient treatment with this drug to complete 24 weeks of treatment under the Initial treatment - Grandfathered patients, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

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

baricitinib 4 mg tablet, 28

11443G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1267.79	40.30	Olumiant [LY]

baricitinib 2 mg tablet, 28

11442F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1267.79	40.30	Olumiant [LY]

BARICITINIB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF- α antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months). Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent

withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialed and failed to demonstrate a response to at least 1 PBS-subsidised TNF- α antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

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

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

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

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

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

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

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

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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

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

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

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

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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

baricitinib 4 mg tablet, 28

11447L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1267.79	40.30	Olumiant [LY]

baricitinib 2 mg tablet, 28

11437Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1267.79	40.30	Olumiant [LY]

■ CLADRIBINE

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

Note Special Pricing Arrangements apply.

Authority required

Relapsing remitting multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed by a neurologist, **AND**
- 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, with 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 a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

The prescriber should request authority approval for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

Authority required

Relapsing remitting multiple sclerosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a neurologist.

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, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.

The prescriber should request authority approval for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

Authority required

Relapsing remitting multiple sclerosis

Treatment Phase: Grandfather treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with 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**
- Patient must have received treatment with this drug for this condition prior to 1 January 2019, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have had at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

The prescriber should request authority approval for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

cladribine 10 mg tablet, 4

11604R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*30816.45	40.30	Mavenclad [SG]

cladribine 10 mg tablet, 1

11603Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3985.16	40.30	Mavenclad [SG]

cladribine 10 mg tablet, 6

11611D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	23150.36	40.30	Mavenclad [SG]

■ EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

everolimus 500 microgram tablet, 60

8841H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	431.97	40.30	Certican [NV]

everolimus 250 microgram tablet, 60

8840G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	218.58	40.30	Certican [NV]

everolimus 1 mg tablet, 60

9352F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1665.35	40.30	Certican [NV]

everolimus 750 microgram tablet, 60

8842J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1268.39	40.30	Certican [NV]

■ FINGOLIMOD

Note No 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

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

 fingolimod 500 microgram capsule, 28

5262Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2210.41	40.30	Gilenya [NV]

■ LEFLUNOMIDE

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Authority required (STREAMLINED)

5766

Severe active psoriatic arthritis

Clinical criteria:

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

leflunomide 10 mg tablet, 30

5449T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	33.04	34.29	^a Arabloc [AV] ^a Ataris 10 [AF] ^a Leflunomide generichealth [HQ]	^a Arava [SW] ^a Leflunomide APOTEX [GX] ^a Leflunomide Sandoz [SZ]

leflunomide 20 mg tablet, 30

5450W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	44.32	40.30	^a Arabloc [AV] ^a Ataris 20 [AF]	^a Arava [SW] ^a Leflunomide APOTEX [GX]

^a Leflunomide generichealth
[HQ]^a Leflunomide Sandoz [SZ]

LEFLUNOMIDE

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Authority required (STREAMLINED)

5681

Severe active rheumatoid arthritis

Clinical criteria:

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

leflunomide 10 mg tablet, 30

8374R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	33.04	34.29	^a Arabloc [AV] ^a Ataris 10 [AF] ^a Leflunomide APOTEX [GX] ^a Leflunomide GH [GQ] ^a Lunava 10 [ZP]	^a Arava [SW] ^a Leflunomide AN [EA] ^a Leflunomide generichealth [HQ] ^a Leflunomide Sandoz [SZ]

leflunomide 20 mg tablet, 30

8375T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	44.32	40.30	^a Arabloc [AV] ^a Ataris 20 [AF] ^a Leflunomide APOTEX [GX] ^a Leflunomide GH [GQ] ^a Lunava 20 [ZP]	^a Arava [SW] ^a Leflunomide AN [EA] ^a Leflunomide generichealth [HQ] ^a Leflunomide Sandoz [SZ]

MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

mycophenolate 180 mg enteric tablet, 120

2150E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	103.72	40.30	Myfortic [NV]

mycophenolate mofetil 500 mg tablet, 50

8650G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	5	..	*153.28	40.30	^a APO-Mycophenolate [TX] ^a Ceptolate [AF] ^a Mycophenolate AN [EA] ^a Pharmacor Mycophenolate 500 [CR]	^a CellCept [RO] ^a MycoCept [RF] ^a Mycophenolate Sandoz [SZ]

mycophenolate 360 mg enteric tablet, 120

2193K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	196.10	40.30	Myfortic [NV]

mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

8651H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	#280.11	40.30	CellCept [RO]

MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Note For item codes 8649F and 1836P, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

mycophenolate mofetil 250 mg capsule, 50

1836P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*153.31	40.30	^a Ceptolate [AF]

mycophenolate mofetil 250 mg capsule, 100

8649F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	5	..	*153.34	40.30	^a APO-Mycophenolate [TX] ^a Mycophenolate Sandoz [SZ]	^a CellCept [RO] ^a Pharmacor Mycophenolate 250 [CR]

■ SIROLIMUS

Caution Careful monitoring of patients is mandatory.

sirolimus 1 mg/mL oral liquid, 60 mL

8725F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	519.32	40.30	Rapamune [PF]

sirolimus 500 microgram tablet, 100

8984W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	332.10	40.30	Rapamune [PF]

sirolimus 1 mg tablet, 100

8724E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	658.99	40.30	Rapamune [PF]

sirolimus 2 mg tablet, 100

8833X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1293.76	40.30	Rapamune [PF]

■ TERIFLUNOMIDE

Caution Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Note No 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

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

teriflunomide 14 mg tablet, 28

2898M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	704.98	40.30	^a Aubagio [GZ]	^a TERIFLAGIO [RW]
						^a Teriflunomide Sandoz [SZ]	

■ TOFACITINIB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having

to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

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

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

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

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

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

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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

tofacitinib 5 mg tablet, 56

10511F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1267.79	40.30	Xeljanz [PF]

▪ TOFACITINIB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

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

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Grandfather treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 May 2019, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **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 prior to initiating non-PBS subsidised treatment with this drug for this condition, **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 prior to initiating non-PBS subsidised treatment with this drug for this condition; 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 prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The 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.

An adequate response to treatment is defined as:

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

either of the following:

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

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

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

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

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

The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course.

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

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

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

- (1) a completed authority prescription form; and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) the date of commencement of this drug; and
- (4) results of the baseline patient assessment prior to initiation of non-PBS subsidised therapy with this drug.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

either of the following:

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

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

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

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

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment or Grandfathered patients - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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

tofacitinib 5 mg tablet, 56

11675L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1267.79	40.30	Xeljanz [PF]

■ TOFACITINIB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
- (iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at

baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

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

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

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

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

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

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

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

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

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

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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

tofacitinib 5 mg tablet, 56

10517M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1267.79	40.30	Xeljanz [PF]

TOFACITINIB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

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

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of

more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level

respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

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

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

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

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

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

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

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

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

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an 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 authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**

- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a 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 the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tofacitinib 5 mg tablet, 56

11690G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1267.79	40.30	Xeljanz [PF]

Tumor necrosis factor alpha (TNF-) inhibitors

■ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

- i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 treatment (new patient or Re-commencement of treatment after more than 5 years break in therapy); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

For first and subsequent continuing courses of PBS-subsidised biological medicine therapy, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

(3) 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 PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

Note Special Pricing Arrangements apply.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

Clinical criteria:

- Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Initial 3 (grandfathered patients) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, **AND**
- The treatment must provide no more than the balance of up to 16 weeks of therapy (new patients or change/re-commencement patients; Initial 1 or Initial 2) or 24 weeks of therapy (Continuing patients or Grandfathered patients).

Treatment criteria:

- Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

10422M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

10400J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10399H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment – balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 1 - New patient restriction to complete a maximum of 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 2 - Recommencement of treatment restriction to complete a maximum of 16 weeks treatment.

Treatment criteria:

- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL pen devices

11133Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2455.87	40.30	Humira [VE]

■ ADALIMUMAB**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have demonstrated an adequate response to treatment with adalimumab, **AND**
- Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of 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 adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

5284D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

5283C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 treatment (new patient or Re-commencement of treatment after more than 5 years break in therapy); or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

For first and subsequent continuing courses of PBS-subsidised biological medicine therapy, it is recommended that a patient

is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

(3) 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 PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

Note Special Pricing Arrangements apply.

Note No applications for increased maximum quantities will 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 40 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, a PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction.

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

10396E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

10420K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10412B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 1 month old at the time of application.

An assessment of the patient's response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include:
 - (i) the Hurley stage grading; and
 - (ii) the AN count; and
 - (iii) the name of the antibiotic/s received for two separate courses each of three months; or
 - (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics
 - (v) a signed patient acknowledgement.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 2 - Recommencement of treatment

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 1 month old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An assessment of the patient's response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommencement of treatment - balance of supply

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include:
 - (i) the Hurley stage grading; and
 - (ii) the AN count.

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices

11132X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3607.74	40.30	Humira [VE]

ADALIMUMAB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and provided to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 3 - Grandfathered patient

Clinical criteria:

- Patient must have been receiving treatment with this drug for this condition prior to 1 July 2017, **AND**
- Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug, **AND**
- Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 12 weeks of treatment if the patient has been treated with this drug for this condition for 12 weeks or longer, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and provided to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Assessment of disease severity must be no more than 1 month old at the time treatment with this drug was initiated.

A maximum of 24 weeks treatment will be authorised under this restriction.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria or recommencement of treatment criteria where there is a break in treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) completed hidradenitis suppurativa PBS authority application supporting Information form which must include:
 - (i) the Hurley stage grading; and
 - (ii) the AN count; and
 - (iii) the name of the antibiotic/s received for two separate courses each of three months; or
 - (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics
 - (v) the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 12 weeks or more of treatment
 - (vi) a signed patient acknowledgement.

adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL pen devices

11137E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2455.87	40.30	Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term biological medicine appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) α -antagonists (adalimumab and infliximab), the α -4 β -7 integrin inhibitor (vedolizumab) and the human IgG1 κ monoclonal antibody (ustekinumab). Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

For subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or

continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

(3) 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 CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Note No applications for increased maximum quantities will 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces:

normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9191R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9189P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 treatment (new patient or Recommencement of treatment after more than 5 years break

in therapy); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

For first and subsequent continuing courses of PBS-subsidised biological medicine therapy, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

(3) 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 PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

Note Special Pricing Arrangements apply.

Note No applications for increased maximum quantities will 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1)

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

- two completed authority prescription forms; and
- a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:
 - the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and
 - details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and
 - the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au).

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) will be authorised.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug 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) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these time-frames, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with infliximab for this condition and have a current PCDAI score of 40 or greater, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation of initial treatment must be in writing and must include:

- two completed authority prescription form; and
- a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:
 - the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and
 - details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug 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) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these time-frames, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

10389T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices

10397F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3607.74	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

10413C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes

10404N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3607.74	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10419J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab or vedolizumab at any one time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, golimumab, infliximab and vedolizumab only.

From 1 June 2018, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, golimumab, infliximab or vedolizumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, vedolizumab treatment prior to 1 June 2018 is considered to start their first cycle as of 1 June 2018. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle.

The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, golimumab, infliximab or vedolizumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of either adalimumab, golimumab, infliximab or vedolizumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with adalimumab, golimumab, infliximab and vedolizumab after 1 June 2018.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with adalimumab, golimumab, infliximab or vedolizumab in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) adalimumab, golimumab, infliximab or vedolizumab therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) an adult patient wishes to re-commence treatment with adalimumab, golimumab, infliximab or vedolizumab following a break in PBS-subsidised therapy with the same agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab. For second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, golimumab, infliximab or vedolizumab a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate adalimumab, golimumab, infliximab or vedolizumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, golimumab, infliximab or vedolizumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab therapy of at least 5 years, must requalify for initial 1 treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents). These above prior treatments must have been received immediately prior to the time the scores of disease severity being used to trial a second or subsequent course are measured.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for moderate to severe ulcerative colitis prior to 1 June 2018 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(a) Initial treatment. Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy - Initial 1 treatment (new patient or Recommencement of treatment after more than 5 years break in therapy); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a biological medicine and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years).

Treatment authorisations under Initial 1 and Initial 2 treatment will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab. For second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the continuing treatment restriction providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure PBS subsidy criteria are met.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(3) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is measured.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

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).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Continuing treatment

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment.

Population criteria:

- Patient must be 6 years of age or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

11121H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

10961X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10960W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, **AND**

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a

treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to

therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

5282B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

5281Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term "biological medicine" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS- subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment. Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1); or
 - a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
 - a patient wishes to re-commence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)
- Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

For subsequent courses of PBS-subsidised adalimumab or infliximab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment

course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Adalimumab patients:

Following the completion of an initial treatment course with adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Infliximab patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

(3) 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 submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition.

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy following a minimum of 12 weeks of therapy.

It is recommended that an application for continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

A maximum of 24 weeks treatment will be authorised under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

8966X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8964T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised

therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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 the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9102C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9034L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB
Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note No 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

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

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 ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of 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 following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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 bDMARD was approved in this cycle and the date of the first application under a 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, **AND**

- 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.

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 ankylosing spondylitis.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9104E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9078T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

▪ **ADALIMUMAB**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
 - a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
 - a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
 - a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
- Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at

baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9100Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8741C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term "biological medicine" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS- subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment. Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1); or
 - a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
 - a patient wishes to re-commence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)
- Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

For subsequent courses of PBS-subsidised adalimumab or infliximab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Adalimumab patients:

Following the completion of an initial treatment course with adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Infliximab patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

(3) 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 submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment (new patient or Re-commencement of treatment after more than 5 years break in therapy - Initial 1)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 1 month old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

It is recommended that an application for continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy following a minimum of 12 weeks of therapy.

It is recommended that an application for continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
 - (ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or Recommencement of treatment after more than 5 years break in therapy), Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) - Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices

8962Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3607.74	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

8965W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes

8961P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3607.74	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8963R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9428F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9427E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.75	40.30	Humira [VE]

▪ **ADALIMUMAB**

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab or vedolizumab at any one time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, golimumab, infliximab and vedolizumab only.

From 1 June 2018, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, golimumab, infliximab or vedolizumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, vedolizumab treatment prior to 1 June 2018 is considered to start their first cycle as of 1 June 2018. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, golimumab, infliximab or vedolizumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of either adalimumab, golimumab, infliximab or vedolizumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with adalimumab, golimumab, infliximab and vedolizumab after 1 June 2018.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with adalimumab, golimumab, infliximab or vedolizumab in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) adalimumab, golimumab, infliximab or vedolizumab therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) an adult patient wishes to re-commence treatment with adalimumab, golimumab, infliximab or vedolizumab following a break in PBS-subsidised therapy with the same agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab. For second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, golimumab, infliximab or vedolizumab a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate adalimumab, golimumab, infliximab or vedolizumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they

are receiving therapy (initial or continuing) with adalimumab, golimumab, infliximab or vedolizumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab therapy of at least 5 years, must requalify for initial 1 treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents). These above prior treatments must have been received immediately prior to the time the scores of disease severity being used to trial a second or subsequent course are measured.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for moderate to severe ulcerative colitis prior to 1 June 2018 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time. Infliximab and adalimumab are PBS-subsidised for moderate to severe disease while only infliximab is PBS-subsidised for acute severe disease.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy - Initial 1 treatment (new patient or Re-commencement of treatment after more than 5 years break in therapy); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) treatment with a biological medicine and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years).

Treatment authorisations under Initial 1 and Initial 2 treatment will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab. For second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the continuing treatment restriction providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure PBS subsidy criteria are met.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) with infliximab or adalimumab at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(3) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the PUCAI score is measured.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient or Re commencement of treatment after more than 5 years break in therapy - Initial 1)

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

- two completed authority prescription forms; and
- a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
 - the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
 - details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - the signed patient acknowledgement or guardian acknowledgement.

For patients weighing 40 kg or greater, a maximum quantity and number of repeats to provide for an initial 16 weeks course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised.

For patients weighing less than 40 kg, a maximum quantity and number of repeats to provide for an initial 16 weeks of this drug consisting of a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised.

Two completed authority prescriptions must be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription must be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with adalimumab, golimumab, infliximab or vedolizumab for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with adalimumab or infliximab for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have failed PBS-subsidised treatment with adalimumab for this condition in the current treatment cycle; OR
- Patient must not have failed PBS-subsidised treatment with adalimumab for this condition in the current treatment cycle more than once if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

Applications for authorisation of change or recommencement treatment must be in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

Two completed authority prescriptions must be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription must be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Initial 1 and Initial 2

Clinical criteria:

- Patient must have received insufficient treatment with this drug under the Initial 1 (new patient or recommencement of treatment after more than 5 years break in therapy) restriction to complete 16 weeks of treatment; OR
- Patient must have received insufficient treatment with this drug under the Initial 2 (Change or Re-commencing of treatment after less than 5 years break in therapy) to complete 16 weeks of treatment.

Population criteria:

- Patient must be 6 years of age or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

11127P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices

10945C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3607.74	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

10955N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes

10972L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3607.74	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10944B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an 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 authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a 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 the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9101B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9033K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1269.75	40.30	Humira [VE]

ADALIMUMAB
Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note No 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

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

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 ankylosing spondylitis.

The application must include details of the NSAIDs trialed, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
 - (ii) a completed BASDAI Assessment Form; and
 - (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
 - (iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

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 disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

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 ankylosing spondylitis.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

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 bDMARD was approved in this cycle and the date of the first application under a 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) 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.

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 ankylosing spondylitis.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9103D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9077R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term biological medicine appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

For subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients

weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

(3) 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 CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Note No applications for increased maximum quantities will 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

- two completed authority prescription forms; and
- a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
 - the date of the most recent clinical assessment; and
 - the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting the Department of Human Services.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the initial dose (i.e. the initial infusion regimen at weeks 0 and 2); OR

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 2 doses (new patients) or 5 repeats (Continuing treatment).

Population criteria:

- Patient must be aged 18 years or older.

Authority approval for sufficient therapy to complete a maximum of 2 initial doses or 5 repeats may be requested by telephone by contacting the Department of Human Services

Note No increase in the maximum quantity or number of units may be authorised.

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices

9187M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3607.74	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9190Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes

9186L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3607.74	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9188N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1269.75	40.30	Humira [VE]

■ ADALIMUMAB**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
 - a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
 - a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
 - a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
- Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab,

baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint

count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9099X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8737W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1269.75	40.30	Humira [VE]

ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence

such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be

assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

- details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

- (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
 - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and

- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

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).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9426D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1269.75	40.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9425C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1269.75	40.30	Humira [VE]

■ CERTOLIZUMAB PEGOL

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11321W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1014.76	40.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10892G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1014.76	40.30	Cimzia [UC]

▪ **CERTOLIZUMAB PEGOL**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to

receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 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.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11326D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1014.76	40.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10896L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1014.76	40.30	Cimzia [UC]

■ CERTOLIZUMAB PEGOL
Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or

continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note No 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 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:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) 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 for all patients) 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.

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 ankylosing spondylitis.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11318Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1014.76	40.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10897M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1014.76	40.30	Cimzia [UC]

■ CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having

to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11325C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1014.76	40.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

3425G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1014.76	40.30	Cimzia [UC]

■ CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months). Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when

commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **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 aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11322X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3008.50	40.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10905Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3008.50	40.30	Cimzia [UC]

■ CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is

submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note No 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

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

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 ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of 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 following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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 bDMARD was approved in this cycle and the date of the first application under a 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- 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.

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 ankylosing spondylitis.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11320T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1014.76	40.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10137M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1014.76	40.30	Cimzia [UC]

■ CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not

submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or commencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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 the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11324B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1014.76	40.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10238W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1014.76	40.30	Cimzia [UC]

■ CERTOLIZUMAB PEGOL
Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID

therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note No 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

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

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 ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
 - (ii) a completed BASDAI Assessment Form; and
 - (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
 - (iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

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 disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

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 ankylosing spondylitis.
- Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

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 bDMARD was approved in this cycle and the date of the first application under a 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11319R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3008.50	40.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10904X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3008.50	40.30	Cimzia [UC]

■ CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note 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)

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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 authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11323Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3008.50	40.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10909E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3008.50	40.30	Cimzia [UC]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine.

Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as

long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the

most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or commencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

9156

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11202N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	Brenzys [MK]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11216H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	Brenzys [MK]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of

treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

7276

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11218K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	Brenzys [MK]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11211C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	Brenzys [MK]

■ **ETANERCEPT**

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to

commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

8092

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

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 bDMARD was issued in this cycle and the date of the first application under a new cycle.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11215G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	Brenzys [MK]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11217J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	Brenzys [MK]

■ ETANERCEPT

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have demonstrated an adequate response to treatment with etanercept, **AND**
- Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of 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 etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a

treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

3448L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

3450N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

3449M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
- (iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- (iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required (STREAMLINED)

8887

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required (STREAMLINED)

8955

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11221N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	Brenzys [MK]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11225T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	Brenzys [MK]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note No 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

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

- Patient must be 18 years or older.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

Each application for continuing treatment with this drug must include a measurement of response to the prior course of therapy. If the response assessment is not submitted, the patient will be deemed to have failed this course of treatment.

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 issued in this cycle and the date of the first application under a 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

11204Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11201M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11196G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
 - a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
 - a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
 - a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
- Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
- Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be

demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

11197H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11220M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11219L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

■ ETANERCEPT

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-

subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4

weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

3445H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

3447K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1049.69	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

3446J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1049.69	40.30	Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
 - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
 - (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
 - (iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
- Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient

is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8638P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9460X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9090K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note No 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

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

The application for first continuing treatment following an initial treatment course must be made following a minimum of 12 weeks of treatment with this drug. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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 bDMARD was issued in this cycle and the date of the first application under a 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8779C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9456Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9086F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

■ ETANERCEPT**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to

receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or commencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

11207W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11198J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11208X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

■ ETANERCEPT
Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will

only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or commencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9036N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9458T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9088H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that

apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

11223Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11222P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11224R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than

5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patients receives the maximum treatment opportunities allowed under these arrangements, it is important that

they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9429G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9462B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9431J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
 - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
 - (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
 - (iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
- Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient

is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated

according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8637N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9459W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9089J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

■ ETANERCEPT
Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note No 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

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patients or recommencement of treatment after a break of 5 years or more)

Clinical criteria:

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment for this condition with a biological disease modifying anti-rheumatic drug (bDMARD) in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialed, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
 - (ii) a completed BASDAI Assessment Form; and
 - (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
 - (iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

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 disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement of treatment after a break of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing or subsequent continuing treatment criteria, patients must have been assessed for response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

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 bDMARD was issued in this cycle and the date of the first application under a 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients or recommencement of treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) – balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or recommencement of treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8778B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9455P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9085E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

▪ **ETANERCEPT**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of

more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level

respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have 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 aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note 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 Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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 authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a 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 the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9035M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9457R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9087G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

■ ETANERCEPT**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised

therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and

scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
 - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
 - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: : Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

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).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9037P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9461Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9091L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1049.69	40.30	^a Brenzys [MK]	^a Enbrel [PF]

■ ETANERCEPT

Note No 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 chronic plaque psoriasis

Treatment Phase: Initial treatment (whole body)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR
- Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
 - (iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Note Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - balance of first supply

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received insufficient therapy under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - completion of course

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

- (i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or
- (ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

- (i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR
- (ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received 16 weeks treatment under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis; OR
- Patient must have received 16 weeks treatment under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, when compared with the pre-etanercept treatment baseline value.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

Note In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

Note The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Whole body)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances

where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must be under 18 years of age.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the whole body, **AND**
- Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, **AND**
- Patient must have demonstrated a response to etanercept and experienced a disease flare; OR
- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

A patient is eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

- (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

- (ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (Face, hand, foot)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR
- Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and face, hand, foot area diagrams including the dates of assessment of the patient's condition

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Note Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment of Re-treatment (Face, hand, foot) - balance of first supply

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances

where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received insufficient therapy under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Face, hand, foot) - completion of course

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received 16 weeks treatment under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis; OR
- Patient must have received 16 weeks treatment under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

Note In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

Note The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Face, hand, foot)

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must be under 18 years of age.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**
- Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, **AND**
- Patient must have demonstrated a response to etanercept and experienced a disease flare; OR
- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

A patient is eligible for re-treatment due to disease flare if:

- (i) all subscores are rated moderate to severe or 2 of the 3 subscores are rated severe to very severe; or
- (ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include :

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
 - (ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

1954W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1049.71	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

1964J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1049.69	40.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

1963H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1049.69	40.30	Enbrel [PF]

■ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab or vedolizumab at any one time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, golimumab, infliximab and vedolizumab only.

From 1 June 2018, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, golimumab, infliximab or vedolizumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, vedolizumab treatment prior to 1 June 2018 is considered to start their first cycle as of 1 June 2018. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle.

The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, golimumab, infliximab or vedolizumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of either adalimumab, golimumab, infliximab or vedolizumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with adalimumab, golimumab, infliximab and vedolizumab after 1 June 2018.

(a) Initial treatment. Applications for initial treatment should be made where:

- (i) an adult patient has received no prior PBS-subsidised treatment with adalimumab, golimumab, infliximab or vedolizumab in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
- (ii) an adult patient has received prior PBS-subsidised (initial or continuing) adalimumab, golimumab, infliximab or vedolizumab therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) an adult patient wishes to re-commence treatment with adalimumab, golimumab, infliximab or vedolizumab following a break in PBS-subsidised therapy with the same agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab. For second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, golimumab, infliximab or vedolizumab a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate adalimumab, golimumab, infliximab or vedolizumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, golimumab, infliximab or vedolizumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab therapy of at least 5 years, must requalify for initial 1 treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents). These above prior treatments must have been received immediately prior to the time the scores of disease severity being used to trial a second or subsequent course are measured.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for moderate to severe ulcerative colitis prior to 1 June 2018 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Note No increase in the maximum number of repeats may be authorised.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Initial 1 and Initial 2

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10).

Population criteria:

- Patient must be aged 18 years or older.

golimumab 100 mg/mL injection, 1 mL pen device

11502J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1251.71	40.30	Simponi [JC]

■ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months). Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate

biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11375Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1299.98	40.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3428K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1299.98	40.30	Simponi [JC]

■ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab or vedolizumab at any one time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, golimumab, infliximab and vedolizumab only.

From 1 June 2018, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, golimumab, infliximab or vedolizumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, vedolizumab treatment prior to 1 June 2018 is considered to start their first cycle as of 1 June 2018. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle.

The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, golimumab, infliximab or vedolizumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of either adalimumab, golimumab, infliximab or vedolizumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with adalimumab, golimumab, infliximab and vedolizumab after 1 June 2018.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with adalimumab, golimumab, infliximab or vedolizumab in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

- (ii) an adult patient has received prior PBS-subsidised (initial or continuing) adalimumab, golimumab, infliximab or vedolizumab therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) an adult patient wishes to re-commence treatment with adalimumab, golimumab, infliximab or vedolizumab following a break in PBS-subsidised therapy with the same agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab. For second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, golimumab, infliximab or vedolizumab a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate adalimumab, golimumab, infliximab or vedolizumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, golimumab, infliximab or vedolizumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab therapy of at least 5 years, must requalify for initial 1 treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents). These above prior treatments must have been received immediately prior to the time the scores of disease severity being used to trial a second or subsequent course are measured.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for moderate to severe ulcerative colitis prior to 1 June 2018 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR

- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be aged 18 years or older.

Application for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (iii) the signed patient acknowledgement.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2, 6 and 10 so that there is adequate time for a response to be demonstrated.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

Patients must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Note Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with adalimumab, golimumab, infliximab or vedolizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with golimumab for this condition in the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

Application for authorisation of change or recommencement treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) Mayo clinical assessment (to demonstrate response to prior treatment).

golimumab 100 mg/mL injection, 1 mL pen device

11382C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3695.32	40.30	Simponi [JC]

■ GOLIMUMAB**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab,

secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the

patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or commencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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 the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11373N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1299.98	40.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3432P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1299.98	40.30	Simponi [JC]

■ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than

5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note No 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

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

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 ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of 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 following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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 bDMARD was approved in this cycle and the date of the first application under a 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- 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.

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 ankylosing spondylitis.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11376R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1299.98	40.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3436W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1299.98	40.30	Simponi [JC]

▪ GOLIMUMAB

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this drug is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 1-10) and 1 of the following:
 - (a) a CRP measurement no greater than 10 mg per L; or
 - (b) a CRP measurement reduced by at least 20% from baseline.

When a patient has either failed or ceased to respond to treatment with this drug for this condition twice, they must have, at a minimum, a 5-year break in PBS-subsidised treatment with this drug for this condition before they are eligible to re-commence under the Initial 1 - New patient or recommencement after a break of more than 5 years.

The 5-year break is measured from the approved date of the last prescription for PBS-subsidised treatment with this drug for this condition to the date of the first application for initial treatment under the Initial 1 restriction.

A patient who has failed treatment with this drug for this condition fewer than twice and who has a break in therapy of less than 5 years may re-commence a further course of treatment with this drug for this condition under the Initial 2 - Re-commencement of treatment after a break of less than 5 years.

The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Non-radiographic axial spondyloarthritis PBS Authority Application - Supporting Information including evidence of adequate response to therapy with PBS-subsidised golimumab.

Note No 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment 3 (grandfathered patient)

Clinical criteria:

- Patient must have previously received non-PBS subsidised therapy with this drug for this condition prior to 1 December 2018, **AND**
- Patient must have demonstrated an adequate response to non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that was relieved by exercise but not rest, prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have had failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must have been sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have had presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have had BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non PBS subsidised treatment with this drug for this condition:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initiating non-PBS subsidised treatment with this drug for this condition.

CRP measurement must be provided with the initial treatment application and must be no more than 1 month old at the time of initiating non-PBS subsidised treatment with this drug for this condition.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

An adequate response to therapy with this drug is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 1-10) and 1 of the following:

- (a) a CRP measurement no greater than 10 mg per L; or
- (b) a CRP measurement reduced by at least 20% from baseline.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Non-radiographic axial spondyloarthritis Grandfathered PBS Authority Application - Supporting Information Form which must include the following:
 - (i) a copy of the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and
 - (ii) evidence of failure to achieve an adequate response to NSAIDs prior to initiating non-PBS subsidised golimumab for this condition ; and
 - (iii) evidence of an adequate response to therapy with non-PBS subsidised golimumab for this condition following a minimum of 12 weeks of treatment with this drug for this condition; and
 - (iv) a copy of the MRI report; and
 - (v) details of the NSAIDs trialled, their doses and duration of treatment or the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication according to the relevant TGA-approved Product Information.

Note No 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing and Grandfathered treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 3 (grandfathered patient) restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of 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 non-radiographic axial spondyloarthritis.

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).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11521J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1299.98	40.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

11516D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1299.98	40.30	Simponi [JC]

■ **GOLIMUMAB**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
 - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
 - (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
 - (iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
- Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate

response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11372M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1299.98	40.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3426H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1299.98	40.30	Simponi [JC]

■ GOLIMUMAB

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment 1 (New patients or recommencement after a break of more than 5 years)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with this drug for this condition in the last 5 years or more, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

- a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

CRP measure must be provided with the initial treatment application and must be no more than 1 month old at the time of application.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

When a patient has either failed or ceased to respond to treatment with this drug for this condition twice, they must have, at a minimum, a 5-year break in PBS-subsidised treatment with this drug for this condition before they are eligible to re-commence under the Initial 1 - New patient or recommencement after a break of more than 5 years.

The 5-year break is measured from the approved date of the last prescription for PBS-subsidised treatment with this drug for this condition to the date of the first application for initial treatment under the Initial 1 restriction.

A patient who has failed treatment with this drug for this condition fewer than twice and who has a break in therapy of less than 5 years may re-commence a further course of treatment with this drug for this condition under the Initial 2 - Re-commencement of treatment after a break of less than 5 years.

The authority application must be made in writing and must include:

- a completed authority prescription form; and

- (b) a completed Non-radiographic axial spondyloarthritis initial PBS Authority Application - Supporting Information Form which must include the following:
- (i) a copy of the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and
 - (ii) a completed BASDAI Assessment Form; and
 - (iii) a copy of C-reactive protein (CRP) test result which must not be more than 1 month old at the time of application ; and
 - (iv) a completed Exercise Program Self Certification Form included in the supporting information form; and
 - (v) a copy of the MRI report; and
 - (vi) details of the NSAIDs trialled, their doses and duration of treatment or the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication according to the relevant TGA-approved Product Information

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Note No 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment 2 (Re-commencement of treatment after a break of less than 5 years)

Clinical criteria:

- Patient must have a documented history of non-radiographic axial spondyloarthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with this drug for this condition within the last five years, **AND**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition more than once within the last five years, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must be accompanied by BASDAI and CRP results of the most recent course of treatment with this drug for this condition within the last 5 years to demonstrate a response to treatment. The results must be conducted following a minimum of 12 weeks of treatment.

When a patient has either failed or ceased to respond to treatment with this drug for this condition twice, they must have, at a minimum, a 5-year break in PBS-subsidised treatment with this drug for this condition before they are eligible to re-commence under the Initial 1 - New patient or recommencement after a break of more than 5 years.

The 5-year break is measured from the approved date of the last prescription for PBS-subsidised treatment with this drug for this condition to the date of the first application for initial treatment under the Initial 1 restriction.

A patient who has failed treatment with this drug for this condition fewer than twice and who has a break in therapy of less than 5 years may re-commence a further course of treatment with this drug for this condition under the Initial 2 - Re-commencement of treatment after a break of less than 5 years.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Non-radiographic axial spondyloarthritis PBS Authority Application - Supporting Information Form including:

1. a completed BASDAI Assessment Form; and
2. a copy of C-reactive protein (CRP) test result

Note No 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment 1 and 2 - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (New patients or recommencement after a break of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Re-commencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

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).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11538G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1299.98	40.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

11560K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1299.98	40.30	Simponi [JC]

■ **GOLIMUMAB**

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity

(i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note No 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

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

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 ankylosing spondylitis.

The application must include details of the NSAIDs trialed, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
 - (ii) a completed BASDAI Assessment Form; and

- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

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 disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

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 ankylosing spondylitis.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

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 bDMARD was approved in this cycle and the date of the first application under a 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

- Patient must have active, or a documented history of active, ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) 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.

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 ankylosing spondylitis.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11361Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1299.98	40.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3434R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1299.98	40.30	Simponi [JC]

■ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not

submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or commencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an 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 authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a 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 the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11365E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1299.98	40.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3430M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1299.98	40.30	Simponi [JC]

■ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised

treatment with either adalimumab, golimumab, infliximab or vedolizumab at any one time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, golimumab, infliximab and vedolizumab only.

From 1 June 2018, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, golimumab, infliximab or vedolizumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, vedolizumab treatment prior to 1 June 2018 is considered to start their first cycle as of 1 June 2018. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, golimumab, infliximab or vedolizumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of either adalimumab, golimumab, infliximab or vedolizumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with adalimumab, golimumab, infliximab and vedolizumab after 1 June 2018.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) an adult patient has received no prior PBS-subsidised treatment with adalimumab, golimumab, infliximab or vedolizumab in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) an adult patient has received prior PBS-subsidised (initial or continuing) adalimumab, golimumab, infliximab or vedolizumab therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) an adult patient wishes to re-commence treatment with adalimumab, golimumab, infliximab or vedolizumab following a break in PBS-subsidised therapy with the same agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab. For second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, golimumab, infliximab or vedolizumab a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate adalimumab, golimumab, infliximab or vedolizumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, golimumab, infliximab or vedolizumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab therapy of at least 5 years, must requalify for initial 1 treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents). These above prior treatments must have been received immediately prior to the time the scores of disease severity being used to trial a second or subsequent course are measured.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for moderate to severe ulcerative colitis prior to 1 June 2018 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Note No 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

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

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).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial 3 (Grandfathered patients)

Clinical criteria:

- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 June 2018, **AND**
- Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR
- Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR
- Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic baseline assessment is not available, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 after receiving doses of this drug at weeks 0, 2, 6 and 10 for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Application for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) and current Mayo clinic or partial Mayo clinic calculation sheet to demonstrate response, including the date of assessment;

(ii) If the baseline Mayo or partial Mayo clinic calculation is not available, reason must be provided;

(iii) the date of commencement of this drug; and

(iv) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Where a grandfather patient has received all four doses at weeks, 0, 2, 6 and 10 by 1 June 2018, one completed authority prescription should be submitted with the application for this drug, specifying a quantity of 1 injection of 100 mg and up to 5 repeats.

Where a grandfather patient has not received doses at weeks 2, 6 and 10 by 1 June 2018, one completed authority prescription should be submitted with the application for this drug specifying a quantity of 1 injection of 100 mg and 2 repeats.

Where a grandfather patient has not received doses at weeks 6 and 10 by 1 June 2018, one completed authority prescription should be submitted with the application for this drug specifying a quantity of 1 injection of 100 mg and 1 repeat.

Where a grandfather patient has not received the dose at week 10 by 1 June 2018, one completed authority prescription should be submitted with the application for this drug specifying a quantity of 1 injection of 100 mg and 0 repeats.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note The patient must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Continuing treatment and Initial 3 (Grandfathered patients)

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient treatment with this drug to complete 24 weeks of treatment under the Initial 3 (Grandfathered patients).

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

golimumab 100 mg/mL injection, 1 mL pen device

11381B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1251.71	40.30	Simponi [JC]

Interleukin inhibitors

■ GUSELKUMAB

Note No 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 TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
- (iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- (iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
 - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
 - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 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).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Whole body, Grandfathered patients

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have received non-PBS subsidised therapy with this drug for this condition prior to 1 February 2019, **AND**
- Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug for this condition (whole body), **AND**
- Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS subsidised treatment with this drug for this condition, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of non-PBS subsidised therapy with this drug) and the most recent PASI assessment; and
 - (ii) the completed PASI calculation sheet demonstrating response.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Face, hand, foot, Grandfathered patients

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have received non-PBS subsidised therapy with this drug for this condition prior to 1 February 2019, **AND**
- Patient must have had disease, prior to treatment with this drug for this condition, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot, **AND**
- Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS subsidised treatment with this drug for this condition, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot or Grandfathered patients - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

guselkumab 100 mg/mL injection, 1 mL syringe

11614G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3786.74	40.30	Tremfya [JC]

IXEKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than

5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological

medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

11033Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
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▪ **IXEKIZUMAB**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and

ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
- (iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- (iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is

submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

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).

ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

11032P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	3412.12	40.30	Taltz [LY]

■ IXEKIZUMAB
Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised

treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**

- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Grandfather treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 March 2019, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS subsidised treatment with this drug 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 prior to initiating non-PBS subsidised treatment with this drug for this condition, **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 prior to initiating non-PBS subsidised treatment with this drug for this condition; 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 prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The 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.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) the date of commencement of this drug; and
- (4) results of the baseline patient assessment prior to initiation of non-PBS subsidised therapy with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment or Grandfathered patients - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

11623R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3412.12	40.30	Taltz [LY]

SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed

treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note 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).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10494H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1457.65	40.30	Cosentyx [NV]

■ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are

eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

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 after a break of less than 5 years) - balance of supply

Clinical criteria:

- Patient must have active, or had a documented history of active ankylosing spondylitis, **AND**
- 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 of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the initial 1 or 2 restrictions.

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 ankylosing spondylitis.

secukinumab 150 mg/mL injection, 1 mL pen device

10893H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	740.46	40.30	Cosentyx [NV]

■ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment

to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction

and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

secukinumab 150 mg/mL injection, 1 mL pen device

10898N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	740.46	40.30	Cosentyx [NV]

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10901R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1457.65	40.30	Cosentyx [NV]

■ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an

alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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

medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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 the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

secukinumab 150 mg/mL injection, 1 mL pen device

10895K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	740.46	40.30	Cosentyx [NV]

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10899P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1457.65	40.30	Cosentyx [NV]

▪ **SECUKINUMAB**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28

weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10425Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1457.65	40.30	Cosentyx [NV]

■ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
 (iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
 Complex Drugs
 Reply Paid 9826
 HOBART TAS 7001

Note No 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

Ankylosing spondylitis

Treatment Phase: Initial treatment – initial 1 (new patients or patients recommencing treatment after a break of 5 years or more)

Clinical criteria:

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

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 ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
 - (ii) a completed BASDAI Assessment Form; and
 - (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
 - (iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

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 disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencing treatment after a break of less than 5 years)

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

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 ankylosing spondylitis.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
 (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.
 A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

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 bDMARD was approved in this cycle and the date of the first application under a new cycle.

secukinumab 150 mg/mL injection, 1 mL pen device

10890E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*2923.87	40.30	Cosentyx [NV]

■ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note 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)

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an 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 authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note 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.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

secukinumab 150 mg/mL injection, 1 mL pen device

10900Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*2923.87	40.30	Cosentyx [NV]

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10894J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*5695.59	40.30	Cosentyx [NV]

■ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with ankylosing spondylitis. Where the term "biological medicine" appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent. (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years)

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(3) 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 BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial 1 treatment with respect to the indices of disease severity. A patient must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Note No 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

Ankylosing spondylitis

Treatment Phase: Initial 3 (grandfather treatment)

Clinical criteria:

- Patient must have confirmed ankylosing spondylitis, defined radiographically (plain X-ray) of Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, with the diagnosis confirmed by a rheumatologist, **AND**
- Patient must have been receiving treatment with this drug for this condition prior to 1 October 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist; OR
 - Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.
- An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
- (a) an ESR measurement no greater than 25 mm per hour; or
 - (b) a CRP measurement no greater than 10 mg per L; or
 - (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The baseline BASDAI assessment must be from immediately prior to commencing treatment with this drug. The patient's current BASDAI assessment and ESR and/or CRP measurements must be no more than 1 month old at the time of application. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form; and
- (c) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (d) a completed BASDAI Assessment Form; and
- (e) a signed patient acknowledgment form;
- (f) the date commencement of this drug;
- (g) results of the baseline BASDAI assessment prior to commencing treatment with this drug.

Patients may qualify for PBS-subsidised treatment under this restriction once only. Further applications for treatment with this drug will be assessed under the continuing treatment restriction.

Note The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

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 ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of 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 following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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 bDMARD was approved in this cycle and the date of the first application under a 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 3 or Continuing treatment – balance of supply

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received insufficient therapy with this drug under the initial 3 treatment restriction to complete 24 weeks of treatment, **AND**
- 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.

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 ankylosing spondylitis.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

secukinumab 150 mg/mL injection, 1 mL pen device

10906B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	740.46	40.30	Cosentyx [NV]

■ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
 - details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
 - at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
 - the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10910F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*5695.59	40.30	Cosentyx [NV]

■ TILDRAKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Whole body, Grandfathered patients

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have received non-PBS subsidised therapy with this drug for this condition prior to 1 February 2019, **AND**
- Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug for this condition (whole body), **AND**
- Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS subsidised treatment with this drug for this condition, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of non-PBS subsidised therapy with this drug) and the most recent PASI assessment; and

(ii) the completed PASI calculation sheet demonstrating response.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Face, hand, foot, Grandfathered patients

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have received non-PBS subsidised therapy with this drug for this condition prior to 1 February 2019, **AND**
- Patient must have had disease, prior to treatment with this drug for this condition, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot, **AND**
- Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS subsidised treatment with this drug for this condition, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot or Grandfathered patients - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tildrakizumab 100 mg/mL injection, 1 mL syringe

11613F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3262.17	40.30	Ilumya [RA]

▪ **TILDRAKIZUMAB**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after

at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
 - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
 - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 28 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).

tildrakizumab 100 mg/mL injection, 1 mL syringe

11616J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3262.17	40.30	Ilumya [RA]

■ TOCILIZUMAB

Note No 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 A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Active giant cell arteritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11721X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	789.22	40.30	Actemra Subcutaneous Injection [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11722Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	789.22	40.30	Actemra ACTPen [RO]

■ TOCILIZUMAB
Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of 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 tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
 (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11730J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	789.22	40.30	Actemra Subcutaneous Injection [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11750K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	789.22	40.30	Actemra ACTPen [RO]

■ TOCILIZUMAB

Note No 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 A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Active giant cell arteritis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

Clinical criteria:

- Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause, **AND**
- Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; OR
- Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; OR
- Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging, **AND**
- Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis, **AND**
- Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; OR
- Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT at diagnosis, **AND**
- The treatment must be in combination with a tapering course of corticosteroids, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

Population criteria:

- Patient must be aged 50 years or older.

Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form;
- (2) a completed Giant Cell Arteritis - Supporting Information Form; and
- (3) documentation that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging;
- (4) documentation that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11743C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	789.22	40.30	Actemra Subcutaneous Injection [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11744D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	789.22	40.30	Actemra ACTPen [RO]

■ TOCILIZUMAB
Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having

to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

10954M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	789.22	40.30	Actemra Subcutaneous Injection [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11567T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	789.22	40.30	Actemra ACTPen [RO]

▪ **TOCILIZUMAB**

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must be 30kg or over, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of 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 tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24

weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11720W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	789.22	40.30	Actemra Subcutaneous Injection [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11742B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	789.22	40.30	Actemra ACTPen [RO]

■ TOCILIZUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
- Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the

relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the

age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11741Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	789.22	40.30	Actemra Subcutaneous Injection [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11725D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	789.22	40.30	Actemra ACTPen [RO]

■ TOCILIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

For a patient who has failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24

months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to the Department of Human Services within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services within sufficient timeframe to allow for authority assessment.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services within sufficient timeframe to allow authority assessment. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Infliximab and etanercept patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

10951J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	789.22	40.30	Actemra Subcutaneous Injection [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11565Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	789.22	40.30	Actemra ACTPen [RO]

■ **TOCILIZUMAB**

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months.

Population criteria:

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) an acknowledgement signed by a parent or authorised guardian.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle.

Population criteria:

- Patient must be under 18 years of age.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The

patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) - balance of supply.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 or 24 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 or 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions for patients 30 kg or over; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions for patients under 30 kg.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with tocilizumab, **AND**
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must be under 30kg, **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of 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 tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) 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 joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete 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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11748H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	789.22	40.30	Actemra Subcutaneous Injection [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11734N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	789.22	40.30	Actemra ACTPen [RO]

■ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up

to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or commencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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 the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

10767Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4349.46	40.30	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological

medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or commencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, AND
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

9305R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4349.46	40.30	Stelara [JC]

■ USTEKINUMAB
Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine.

Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

10774C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4349.46	40.30	Stelara [JC]

■ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological

medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tildrakizumab only).

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the

Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
 - details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

9304Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4349.46	40.30	Stelara [JC]

■ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term biological medicine appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab, vedolizumab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, or vedolizumab treatment prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab, vedolizumab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised therapy with adalimumab, infliximab, vedolizumab or ustekinumab in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab, vedolizumab or ustekinumab and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with adalimumab, infliximab, vedolizumab or ustekinumab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab, 14 weeks of therapy for vedolizumab and 16 weeks for ustekinumab.

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

For subsequent courses of PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, infliximab, vedolizumab or ustekinumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to

24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate adalimumab, infliximab, vedolizumab or ustekinumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab, vedolizumab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

(3) 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 CDAI or evidence of intestinal inflammation submitted with the first authority application for adalimumab, infliximab, vedolizumab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

(6) Patients 'grandfathered' onto PBS-subsidised treatment with ustekinumab.

A patient who commenced treatment with ustekinumab for severe Crohn disease prior to 1 September 2017 and who continues to receive treatment at the time of application may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR

- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
 - (iv) the date of the most recent clinical assessment; and
 - (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

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

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

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

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Note No increase in the maximum quantity or number of units may be authorised.

Note Increase in the maximum number of repeats of up to 2 may be authorised in patients whose dosing frequency is every 8 weeks.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment (Grandfather)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 September 2017, **AND**
- Patient must be receiving treatment with ustekinumab at the time of application, **AND**
- Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease Grandfathered PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
 - (iv) the date of the most recent clinical assessment; and
 - (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note No applications for increased maximum quantities will be authorised.

Note Increase in the maximum number of repeats of up to two may be authorised in patients whose dosing frequency is every 8 weeks.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment or Grandfathered treatment

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Grandfathered treatment restriction to complete 24 weeks of treatment.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services.

Note No increase in the maximum quantity or number of units may be authorised.

Note Applications for authority to prescribe may be made by phone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

11178H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*8616.75	40.30	Stelara [JC]

Calcineurin inhibitors**■ CICLOSPORIN****Caution** Careful monitoring of patients is mandatory.**ciclosporin 100 mg capsule, 30**

8660T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*309.21	40.30	^a Cyclosporin Sandoz [SZ]	^a Neoral 100 [NV]

ciclosporin 25 mg capsule, 30

8658Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*80.77	40.30	^a Cyclosporin Sandoz [SZ]	^a Neoral 25 [NV]

ciclosporin 10 mg capsule, 60

8657P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*91.49	40.30	Neoral 10 [NV]

ciclosporin 100 mg/mL oral liquid, 50 mL

8661W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*708.03	40.30	Neoral [NV]

ciclosporin 50 mg capsule, 30

8659R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*155.65	40.30	^a Cyclosporin Sandoz [SZ]	^a Neoral 50 [NV]

■ TACROLIMUS**Caution** Careful monitoring of patients is mandatory.**tacrolimus 750 microgram capsule, 100**

10870D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	213.84	40.30	Tacrolimus Sandoz [SZ]

tacrolimus 5 mg modified release capsule, 30

5451X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	422.74	40.30	^a ADVAGRAF XL [LQ]	^a Prograf XL [LL]

tacrolimus 5 mg capsule, 50

8648E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	615.26	40.30	^a Pacrolim [AF] ^a Prograf [LL] ^a TACROLIMUS APOTEX [TX]	^a Pharmacor Tacrolimus 5 [CR] ^a Tacrograf [RW] ^a Tacrolimus Sandoz [SZ]

tacrolimus 1 mg capsule, 100

8647D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	249.34	40.30	^a Pacrolim [AF] ^a Prograf [LL] ^a TACROLIMUS APOTEX [TX]	^a Pharmacor Tacrolimus 1 [CR] ^a Tacrograf [RW] ^a Tacrolimus Sandoz [SZ]

tacrolimus 2 mg capsule, 100

10871E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	561.60	40.30	Tacrolimus Sandoz [SZ]

tacrolimus 500 microgram modified release capsule, 30

5299X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	51.82	40.30	^a ADVAGRAF XL [LQ]	^a Prograf XL [LL]

tacrolimus 500 microgram capsule, 100

8646C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	129.43	40.30	^a Pacrolim [AF] ^a Prograf [LL] ^a TACROLIMUS APOTEX [TX]	^a Pharmacor Tacrolimus 0.5 [CR] ^a Tacrograf [RW] ^a Tacrolimus Sandoz [SZ]

tacrolimus 1 mg modified release capsule, 60

5300Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	153.02	40.30	^a ADVAGRAF XL [LQ]	^a Prograf XL [LL]

Other immunosuppressants

■ AZATHIOPRINE

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.

azathioprine 50 mg tablet, 100

2687K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	32.19	33.44	^a APO-Azathioprine [TX] ^a Azathioprine AN [EA] ^a Azathioprine Sandoz [SZ] ^a Imuran [AS]	^a Azapin [RW] ^a Azathioprine GH [GQ] ^a Imazan [ER] ^a Thioprine 50 [AF]

azathioprine 25 mg tablet, 100

2688L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.64	24.89	^a APO-Azathioprine [TX] ^a Azathioprine Sandoz [SZ]	^a Azathioprine GH [GQ] ^a Imuran [AS]

■ DIMETHYL FUMARATE

Note Special Pricing Arrangements apply.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

dimethyl fumarate 120 mg enteric capsule, 14

2943X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*638.87	40.30	Tecfidera [BD]

■ DIMETHYL FUMARATE

Note No 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

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

dimethyl fumarate 240 mg enteric capsule, 56

2966D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1287.90	40.30	Tecfidera [BD]

■ DIMETHYL FUMARATE

Note No 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

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

dimethyl fumarate 120 mg enteric capsule, 14

2896K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*638.87	40.30	Tecfidera [BD]

■ METHOTREXATE**methotrexate 2.5 mg tablet, 30**

1622J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	17.31	18.56	Methoblastin [PF]

methotrexate 10 mg tablet, 15

2272N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	23.58	24.83	Methoblastin [PF]

■ METHOTREXATE**Restricted benefit**

Patients requiring doses greater than 20 mg per week

methotrexate 10 mg tablet, 50

1623K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	51.80	40.30	Methoblastin [PF]

■ METHOTREXATE

Note Pharmaceutical benefits that have the form methotrexate Injection 15 mg/0.3 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 15 mg/0.6 mL pre-filled syringe are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**7488**

Severe active rheumatoid arthritis

Clinical criteria:

- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

Authority required (STREAMLINED)**7518**

Severe psoriasis

Clinical criteria:

- The condition must not have adequately responded to topical treatment, **AND**
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe

11268C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*88.87	40.30	^a Trexject [LM]

methotrexate 15 mg/0.6 mL injection, 4 x 0.6 mL syringes

11508Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	88.89	40.30	^a Methoblastin PFS [PF]

■ METHOTREXATE

Note Pharmaceutical benefits that have the form methotrexate Injection 7.5 mg/0.15 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 7.5 mg/0.3 mL pre-filled syringe are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**7488**

Severe active rheumatoid arthritis

Clinical criteria:

- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

Authority required (STREAMLINED)

7518

Severe psoriasis

Clinical criteria:

- The condition must not have adequately responded to topical treatment, **AND**
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe

11275K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*88.87	40.30	^a Trexject [LM]

methotrexate 7.5 mg/0.3 mL injection, 4 x 0.3 mL syringes

11525N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	88.89	40.30	^a Methoblastin PFS [PF]

■ METHOTREXATE

Note Pharmaceutical benefits that have the form methotrexate Injection 10 mg/0.2 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 10 mg/0.4 mL pre-filled syringe are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**7488**

Severe active rheumatoid arthritis

Clinical criteria:

- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

Authority required (STREAMLINED)**7518**

Severe psoriasis

Clinical criteria:

- The condition must not have adequately responded to topical treatment, **AND**
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe

11283W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*88.87	40.30	^a Trexject [LM]

methotrexate 10 mg/0.4 mL injection, 4 x 0.4 mL syringes

11526P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	88.89	40.30	^a Methoblastin PFS [PF]

■ METHOTREXATE

Note Pharmaceutical benefits that have the form methotrexate Injection 20 mg/0.4 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 20 mg/0.8 mL pre-filled syringe are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**7488**

Severe active rheumatoid arthritis

Clinical criteria:

- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

Authority required (STREAMLINED)**7518**

Severe psoriasis

Clinical criteria:

- The condition must not have adequately responded to topical treatment, **AND**
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

methotrexate 20 mg/0.4 mL injection, 0.4 mL syringe

11288D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*88.87	40.30	^a Trexject [LM]

methotrexate 20 mg/0.8 mL injection, 4 x 0.8 mL syringes

11509R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	88.89	40.30	^a Methoblastin PFS [PF]

■ METHOTREXATE

Note Pharmaceutical benefits that have the form methotrexate Injection 25 mg/0.5 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 25 mg/mL pre-filled syringe are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**7488**

Severe active rheumatoid arthritis

Clinical criteria:

- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

Authority required (STREAMLINED)

7518

Severe psoriasis

Clinical criteria:

- The condition must not have adequately responded to topical treatment, **AND**
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe

11295L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*88.87	40.30	^a Trexject [LM]

methotrexate 25 mg/mL injection, 4 x 1 mL syringes

11544N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	88.89	40.30	^a Methoblastin PFS [PF]

■ **PIRFENIDONE**

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No 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

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition.

Treatment criteria:

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

pirfenidone 801 mg tablet, 90

11410M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3067.12	40.30	Esbriet [RO]

■ **PIRFENIDONE**

Note No 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

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

Clinical criteria:

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition.

Treatment criteria:

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must not have an acute respiratory infection at the time of FVC testing.

Application for authorisation of initial treatment must be in writing and must include:

- a) a completed authority prescription form; and
- b) a completed IPF Authority Application Supporting Information Form; and
- c) a signed patient acknowledgement.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or re-commencement of treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition.

Treatment criteria:

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition.

Treatment criteria:

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

pirfenidone 267 mg tablet, 90

11406H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*3067.12	40.30	Esbriet [RO]

pirfenidone 267 mg capsule, 270

11136D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3067.12	40.30	Esbriet [RO]

■ MUSCULO-SKELETAL SYSTEM

■ ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS

Acetic acid derivatives and related substances

■ DICLOFENAC

diclofenac sodium 100 mg suppository, 20

1302M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	2	3	..	*27.91	29.16	Voltaren 100 [NV]

diclofenac sodium 100 mg suppository, 20

5079H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*27.91	29.16	Voltaren 100 [NV]

■ DICLOFENAC

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

diclofenac sodium 50 mg enteric tablet, 50

1300K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	13.53	14.78	^a APO-Diclofenac [TX] ^a Diclofenac Amneal [ED] ^a Diclofenac Sandoz [SZ] ^a Pharmacor Diclofenac 50 [CR]	^a Clonac 50 [RW] ^a Diclofenac AN [EA] ^a Fenac [AF]
			^B 3.46	16.99	14.78	^a Voltaren 50 [NV]	

diclofenac sodium 25 mg enteric tablet, 50

1299J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*14.43	15.68	^a APO-Diclofenac [TX] ^a Diclofenac Amneal [ED] ^a Diclofenac Sandoz [SZ]	^a Clonac 25 [RW] ^a Diclofenac AN [EA] ^a Fenac 25 [AF]
			^B 3.44	*17.87	15.68	^a Voltaren 25 [NV]	

■ DICLOFENAC**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

diclofenac sodium 50 mg enteric tablet, 50

5077F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.53	14.78	^a APO-Diclofenac [TX] ^a Diclofenac Amneal [ED] ^a Diclofenac Sandoz [SZ] ^a Pharmacor Diclofenac 50 [CR]	^a Clonac 50 [RW] ^a Diclofenac AN [EA] ^a Fenac [AF]
			^B 3.46	16.99	14.78	^a Voltaren 50 [NV]	

diclofenac sodium 25 mg enteric tablet, 50

5076E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	2	..	..	*14.43	15.68	^a APO-Diclofenac [TX] ^a Diclofenac Amneal [ED] ^a Diclofenac Sandoz [SZ]	^a Clonac 25 [RW] ^a Diclofenac AN [EA] ^a Fenac 25 [AF]
			^B 3.44	*17.87	15.68	^a Voltaren 25 [NV]	

■ INDOMETACIN**indometacin 100 mg suppository, 20**

2757D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*25.47	26.72	Indocid [AS]

indometacin 100 mg suppository, 20

5128X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*25.47	26.72	Indocid [AS]

■ INDOMETACIN**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

indometacin 25 mg capsule, 50

2454E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*17.09	18.34	^a Arthrexin [AF]
			^B 4.04	*21.13	18.34	^a Indocid [AS]

■ INDOMETACIN**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

indometacin 25 mg capsule, 50

5126T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*17.09	18.34	^a Arthrexin [AF]
			^B 4.04	*21.13	18.34	^a Indocid [AS]

Oxicams**MELOXICAM**

Note Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

Note The use of this drug for the treatment of the following conditions is not subsidised through the PBS:

- (a) acute pain;
- (b) soft tissue injury;
- (c) arthrosis without an inflammatory component.

Restricted benefit

Osteoarthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

Restricted benefit

Rheumatoid arthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

meloxicam 7.5 mg tablet, 30

8561N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	14.28	15.53	^a APO-Meloxicam [TX]	^a Chem mart Meloxicam 7.5 mg [CH]
						^a CIPLA MELOXICAM 7.5 [LR]	^a Meloxiauro 7.5 [DO]
						^a Meloxibell [GQ]	^a Meloxicam AN [EA]
						^a Meloxicam-GA [ED]	^a Meloxicam Sandoz [SZ]
						^a Movalis 7.5 [RW]	^a Moxicam 7.5 [AF]
						^a Pharmacor Meloxicam 7.5 [CR]	^a Terry White Chemists Meloxicam 7.5 mg [TW]
			^B 3.00	17.28	15.53	^a Mobic [BY]	

meloxicam 7.5 mg capsule, 30

8887R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	14.28	15.53	^a APO-Meloxicam [TX]	^a Chem mart Meloxicam [CH]
						^a Meloxicam Sandoz [SZ]	^a Movalis 7.5 [RW]
						^a Moxicam [AF]	^a Terry White Chemists Meloxicam [TW]
			^B 3.00	17.28	15.53	^a Mobic [BY]	

MELOXICAM

Note Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

Note The use of this drug for the treatment of the following conditions is not subsidised through the PBS:

- (a) acute pain;
- (b) soft tissue injury;
- (c) arthrosis without an inflammatory component.

Restricted benefit

Osteoarthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

Restricted benefit

Rheumatoid arthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

meloxicam 15 mg capsule, 30

8888T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	15.57	16.82	^a APO-Meloxicam [TX]	^a Chem mart Meloxicam [CH]
						^a Meloxicam Sandoz [SZ]	^a Movalis 15 [RW]
						^a Moxicam [AF]	^a Terry White Chemists Meloxicam [TW]
			^B 3.00	18.57	16.82	^a Mobic [BY]	

meloxicam 15 mg tablet, 30

8562P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	15.57	16.82	^a APO-Meloxicam [TX]	^a Chem mart Meloxicam 15 mg [CH]
						^a CIPLA MELOXICAM 15 [LR]	^a Meloxiauro 15 [DO]
						^a Meloxibell [GQ]	^a Meloxicam AN [EA]
						^a Meloxicam-GA [ED]	^a Meloxicam Sandoz [SZ]
						^a Movalis 15 [RW]	^a Moxicam 15 [AF]
						^a Pharmacor Meloxicam 15 [CR]	^a Terry White Chemists Meloxicam 15 mg [TW]
			^B 3.00	18.57	16.82	^a Mobic [BY]	

PIROXICAM**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

piroxicam 10 mg capsule, 50

1897W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	16.51	17.76	^a APO-Piroxicam [TX]	^a GenRx Piroxicam [GX]
						^a Mobilis 10 [AF]	
			^B 8.00	24.51	17.76	^a Feldene [PF]	

piroxicam 10 mg capsule, 50

5203W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.51	17.76	^a APO-Piroxicam [TX]	^a GenRx Piroxicam [GX]
						^a Mobilis 10 [AF]	
			^B 8.00	24.51	17.76	^a Feldene [PF]	

piroxicam 20 mg dispersible tablet, 25

1896T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	3	..	16.26	17.51	^a Mobilis D-20 [AF]	
			^B 8.00	24.26	17.51	^a Feldene-D [PF]	

piroxicam 20 mg dispersible tablet, 25

5202T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
DP	1	..	..	16.26	17.51	^a Mobilis D-20 [AF]	
			^B 8.00	24.26	17.51	^a Feldene-D [PF]	

piroxicam 10 mg dispersible tablet, 50

1895R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	3	..	16.51	17.76	Mobilis D-10 [AF]	

piroxicam 10 mg dispersible tablet, 50

5201R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
DP	1	..	..	16.51	17.76	Mobilis D-10 [AF]	

piroxicam 20 mg capsule, 25

1898X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	16.26	17.51	^a APO-Piroxicam [TX]	^a GenRx Piroxicam [GX]
						^a Mobilis 20 [AF]	
			^B 8.00	24.26	17.51	^a Feldene [PF]	

piroxicam 20 mg capsule, 25

5204X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.26	17.51	^a APO-Piroxicam [TX]	^a GenRx Piroxicam [GX]
						^a Mobilis 20 [AF]	
			^B 8.00	24.26	17.51	^a Feldene [PF]	

*Propionic acid derivatives***IBUPROFEN****ibuprofen 400 mg tablet, 30**

3192B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP MW	1	..	..	13.40	14.65	^a APO-Ibuprofen 400 [TX]	
			^B 3.00	16.40	14.65	^a Brufen [GO]	

ibuprofen 400 mg tablet, 30

5124Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
DP	1	..	..	13.40	14.65	^a APO-Ibuprofen 400 [TX]	
			^B 3.00	16.40	14.65	^a Brufen [GO]	

■ **IBUPROFEN****Restricted benefit**

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

ibuprofen 400 mg tablet, 30

3190X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*17.23	18.48	^a APO-Ibuprofen 400 [TX]
			^B 9.00	*26.23	18.48	^a Brufen [GO]

■ **IBUPROFEN****Restricted benefit**

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

ibuprofen 400 mg tablet, 30

5123P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	3	..	..	*17.23	18.48	^a APO-Ibuprofen 400 [TX]
			^B 9.00	*26.23	18.48	^a Brufen [GO]

■ **KETOPROFEN****Restricted benefit**

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

ketoprofen 200 mg modified release capsule, 28

1590Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	22.51	23.76	^a Oruvail SR [AV]
			^B 1.92	24.43	23.76	^a Orudis SR 200 [SW]

ketoprofen 200 mg modified release capsule, 28

5136H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	22.51	23.76	^a Oruvail SR [AV]
			^B 1.92	24.43	23.76	^a Orudis SR 200 [SW]

■ **NAPROXEN****Restricted benefit**

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

naproxen 500 mg tablet, 50

1659H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.85	18.10	^a Inza 500 [AF]
			^B 1.12	17.97	18.10	^a Naprosyn [IX]

naproxen 750 mg modified release tablet, 28

1614Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.40	17.65	^a Proxen SR 750 [IY]
			^B 1.06	17.46	17.65	^a Naprosyn SR750 [IX]

naproxen 1 g modified release tablet, 28

1615B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	18.04	19.29	^a Proxen SR 1000 [IY]
			^B 1.12	19.16	19.29	^a Naprosyn SR1000 [IX]

naproxen 250 mg tablet, 50

1674D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*18.75	20.00	^a Inza 250 [AF]
			^B 2.24	*20.99	20.00	^a Naprosyn [IX]

■ NAPROXEN

Authority required (STREAMLINED)

4159

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component, **AND**
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

Authority required (STREAMLINED)

4124

Bone pain

Clinical criteria:

- The condition must be due to malignant disease, **AND**
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

naproxen 125 mg/5 mL oral liquid, 474 mL

1658G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	3	..	121.66	40.30	Phebra Naproxen Suspension [FF]

■ NAPROXEN

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

naproxen 500 mg tablet, 50

5177L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	16.85	18.10	^a Inza 500 [AF]
			^B 1.12	17.97	18.10	^a Naprosyn [IX]

naproxen 750 mg modified release tablet, 28

5178M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	16.40	17.65	^a Proxen SR 750 [IY]
			^B 1.06	17.46	17.65	^a Naprosyn SR750 [IX]

naproxen 1 g modified release tablet, 28

5179N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	18.04	19.29	^a Proxen SR 1000 [IY]
			^B 1.12	19.16	19.29	^a Naprosyn SR1000 [IX]

naproxen 250 mg tablet, 50

5176K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*18.75	20.00	^a Inza 250 [AF]
			^B 2.24	*20.99	20.00	^a Naprosyn [IX]

■ NAPROXEN

Note Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

naproxen sodium 550 mg tablet, 50

1795L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	17.00	18.25	^a Crysanal [IY]
			^B 1.89	18.89	18.25	^a Anaprox 550 [IX]

■ NAPROXEN

Note Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

Restricted benefit

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

- The condition must have an inflammatory component.

Restricted benefit

Bone pain

Clinical criteria:

- The condition must be due to malignant disease.

naproxen sodium 550 mg tablet, 50

5186Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	17.00	18.25	^a Crysanal [IY]
			^B 1.89	18.89	18.25	^a Anaprox 550 [IX]

Fenamates

■ MEFENAMIC ACID

Restricted benefit

Dysmenorrhoea

Restricted benefit

Menorrhagia

mefenamic acid 250 mg capsule, 50

1824B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.78	21.03	Ponstan [PF]

Coxibs

■ CELECOXIB

Note The use of this drug for the treatment of the following conditions is not subsidised through the PBS:

- (a) acute pain;
- (b) soft tissue injury;
- (c) arthrosis without an inflammatory component.

Restricted benefit

Osteoarthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

Restricted benefit

Rheumatoid arthritis

Clinical criteria:

- The treatment must be for symptomatic treatment.

celecoxib 100 mg capsule, 60

8439E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	16.43	17.68	^a APO-Celecoxib [TX]	^a Blooms the Chemist Celecoxib [IB]
						^a Celaxib [AF]	^a Celebrex [PF]
						^a Celecoxib AN [EA]	^a Celecoxib BTC [JB]
						^a Celecoxib GH [GQ]	^a Celecoxib Sandoz [SZ]
						^a Celexi [RW]	^a Chem mart Celecoxib [CH]
						^a GenRx Celecoxib [GX]	^a Terry White Chemists Celecoxib [TW]

celecoxib 200 mg capsule, 30

8440F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	16.43	17.68	^a APO-Celecoxib [TX]	^a Blooms the Chemist Celecoxib [IB]
						^a Celaxib [AF]	^a Celebrex [PF]
						^a Celecoxib AN [EA]	^a Celecoxib BTC [JB]
						^a Celecoxib GH [GQ]	^a Celecoxib Sandoz [SZ]
						^a Celexi [RW]	^a Chem mart Celecoxib [CH]
						^a GenRx Celecoxib [GX]	^a Terry White Chemists Celecoxib [TW]

SPECIFIC ANTIRHEUMATIC AGENTS

Quinolines

■ HYDROXYCHLOROQUINE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

MUSCULO-SKELETAL SYSTEM

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

hydroxychloroquine sulfate 200 mg tablet, 100

1512N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	25.54	26.79	^a APO- Hydroxychloroquine [TX]	^a Hequinel [RW]
						^a Hydroxychloroquine AN [EA]	^a Hydroxychloroquine GH [GQ]
						^a Plaquenil [SW]	

Gold preparations

■ AURANOFIN

Caution Regular blood and urine checks are essential.

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.

auranofin 3 mg tablet, 60

1095P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	204.57	40.30	Ridaura [GH]

auranofin 3 mg capsule, 60

2022K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	774.04	40.30	Ridaura [BZ]

■ SODIUM AUROTHIOMALATE

Caution Regular blood and urine checks are essential.

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.

sodium aurothiomate 20 mg/0.5 mL injection, 10 x 0.5 mL ampoules

2017E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	98.82	40.30	Myocrisin [SW]

sodium aurothiomate 10 mg/0.5 mL injection, 10 x 0.5 mL ampoules

2016D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	68.25	40.30	Myocrisin [SW]

sodium aurothiomate 50 mg/0.5 mL injection, 10 x 0.5 mL ampoules

2018F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	119.32	40.30	Myocrisin [SW]

Penicillamine and similar agents

■ PENICILLAMINE

Caution Regular blood and urine checks are essential.

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.

penicillamine 250 mg tablet, 100

2838J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	45.90	40.30	D-Penamine [AL]

penicillamine 125 mg tablet, 100

2721F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	40.62	40.30	D-Penamine [AL]

■ MUSCLE RELAXANTS

MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

Other centrally acting agents

■ BACLOFEN

baclofen 25 mg tablet, 100

2730Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	33.29	34.54	^a APO-Baclofen [TX]	^a Clofen 25 [AF]

NP	baclofen 10 mg tablet, 100							^a GenRx Baclofen [GX]	^a Lioresal 25 [NV]
								^a Stelax 25 [RW]	
2729P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		Brand Name and Manufacturer	
NP	1	5	..	21.46	22.71	^a APO-Baclofen [TX]		^a Clofen 10 [AF]	
						^a GenRx Baclofen [GX]		^a Lioresal 10 [NV]	
						^a Stelax 10 [RW]			

MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS*Dantrolene and derivatives***■ DANTROLENE****Restricted benefit**

Chronic spasticity

dantrolene sodium hemiheptahydrate 50 mg capsule, 100

1780Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	2	..	76.59	40.30	Dantrium [PF]	

dantrolene sodium hemiheptahydrate 25 mg capsule, 100

1779P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	2	..	76.06	40.30	Dantrium [PF]	

■ ANTIGOUT PREPARATIONS**ANTIGOUT PREPARATIONS***Preparations inhibiting uric acid production***■ ALLOPURINOL****Note** The dose should be adjusted in accordance with renal function.**allopurinol 100 mg tablet, 200**

2600W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		Brand Name and Manufacturer	
NP	1	2	..	16.34	17.59	^a Allopurinol APOTEX [GX]		^a Allopurinol Sandoz [SZ]	
						^a Allosig [RF]		^a APO-Allopurinol [TX]	
						^a Pro gout 100 [AF]			
			^b 3.47	19.81	17.59	^a Zyloprim [RW]			

allopurinol 300 mg tablet, 60

2604C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer		Brand Name and Manufacturer	
NP	1	2	..	15.00	16.25	^a Allopurinol APOTEX [GX]		^a Allopurinol Sandoz [SZ]	
						^a Allosig [RF]		^a APO-Allopurinol [TX]	
						^a Pro gout 300 [AF]			
			^b 3.48	18.48	16.25	^a Zyloprim [RW]			

■ FEBUXOSTAT**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.

Authority required (STREAMLINED)**8921**

Chronic gout

Clinical criteria:

- The condition must be either chronic gouty arthritis or chronic tophaceous gout, **AND**
- Patient must have a medical contraindication to allopurinol; OR
- Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

febuxostat 80 mg tablet, 28

10445R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	51.33	40.30	Adenuric [FK]	

*Preparations increasing uric acid excretion***■ PROBENECID****probenecid 500 mg tablet, 100**

1940D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	1	5	..	62.63	40.30	Pro-Cid [FF]	

Preparations with no effect on uric acid metabolism

■ COLCHICINE

colchicine 500 microgram tablet, 30

3410L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.46	16.71	^a Lengout [LN]
			^b 2.90	18.36	16.71	^a Colgout [AS]

■ DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

■ ALENDRONATE

Restricted benefit

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

alendronate 70 mg tablet, 4

8511Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.39	16.64	^a Alendrobell 70mg [GQ]	^a Alendronate Sandoz [SZ]
						^a Alendro Once Weekly [RW]	^a APO-Alendronate [TX]
						^a Densate 70 [DO]	^a Fonat [AL]

■ IBANDRONATE

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.

Restricted benefit

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

ibandronate 50 mg tablet, 28

9357L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	286.51	40.30	Bondronat [IX]

■ PAMIDRONATE DISODIUM

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.

Restricted benefit

Symptomatic Paget disease of bone

pamidronate disodium 30 mg/10 mL injection, 10 mL vial

8462J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*70.91	40.30	Pamisol [PF]

pamidronate disodium 15 mg/5 mL injection, 5 mL vial

8461H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	..	..	*70.87	40.30	Pamisol [PF]

pamidronate disodium 60 mg/10 mL injection, 10 mL vial

8463K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	70.90	40.30	Pamisol [PF]

■ RISEDRONATE

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.

Restricted benefit

Symptomatic Paget disease of bone

risedronate sodium 30 mg tablet, 28

8482K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	175.48	40.30	Actonel [TT]

■ RISEDRONATE

Restricted benefit

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

risedronate sodium 5 mg tablet, 28

8481J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	35.49	36.74	Actonel [TT]

risedronate sodium 35 mg tablet, 4

8621R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	35.49	36.74	^a Acris Once-a-Week [AF] ^a Risedronate AN [EA] ^a Risedro once a week [RW]	^a APO-Risedronate [TX] ^a Risedronate Sandoz [SZ]

risedronate sodium 150 mg tablet, 1

9391G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	37.51	38.76	^a Acris Once-a-Month [AF] ^a APO-Risedronate [TX]	^a Actonel Once-a-Month [TT]

risedronate sodium 35 mg enteric tablet, 4

8972F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	35.49	36.74	Actonel EC [TT]

■ ZOLEDRONIC ACID

Note Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**5710**

Symptomatic Paget disease of bone

Only 1 treatment each year per patient will be PBS-subsidised

zoledronic acid 5 mg/100 mL injection, 100 mL bag

10571J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	264.26	40.30	^a Ostira [PF]

zoledronic acid 5 mg/100 mL injection, 100 mL vial

9350D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	264.26	40.30	^a Aclasta [HX] ^a Zoledasta [TX]	^a Osteovan [SZ]

■ ZOLEDRONIC ACID

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Note Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**6308**

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
 - Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
 - Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
 - Patient must not receive more than one PBS-subsidised treatment per year.
- The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)**6313**

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less, **AND**
 - Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
 - Patient must not receive more than one PBS-subsidised treatment per year.
- The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)**6318**

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

zoledronic acid 5 mg/100 mL injection, 100 mL bag

10555M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	264.26	40.30	^a Ostira [PF]

zoledronic acid 5 mg/100 mL injection, 100 mL vial

9288W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	264.26	40.30	^a Aclasta [HX] ^a Zoledasta [TX]	^a Osteovan [SZ]

Bisphosphonates, combinations**■ ALENDRONATE + COLECALCIFEROL**

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)**6306**

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
 - Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
 - Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
- The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)**6325**

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
 - Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
- The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)**6319**

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
 - Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
- The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
- A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

9183H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.33	19.58	^a ALENDRONATE PLUS D3 70mg/140ug APOTEX [GX]	^a Alendronate plus D3-DRLA [RZ]
						^a Alendronate Plus D3 Sandoz [SZ]	^a APO-Alendronate Plus D3 70 mg/140 mcg [TX]
						^a Dronalen Plus [AL]	^a FonatPlus [AF]
			^B 4.00	22.33	19.58	^a Fosamax Plus 70 mg/140 mcg [MK]	

■ ALENDRONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Note Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

Authority required (STREAMLINED)

6307

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6320

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6315

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

alendronate 70 mg + colecalciferol 70 microgram tablet, 4

9012H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.33	19.58	^a ALENDRONATE PLUS D3 70mg/70ug APOTEX [GX]	^a Alendronate plus D3-DRLA [RZ]
						^a Alendronate Plus D3 Sandoz [SZ]	^a APO-Alendronate Plus D3 70 mg/70 mcg [TX]
						^a FonatPlus [AF]	
			^B 4.00	22.33	19.58	^a Fosamax Plus [MK]	

▪ **ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE**

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

6306

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6325

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6319

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack

9351E

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	23.22	24.47	^a Dronalen Plus D-Cal [AF]	^a ReddyMax Plus D-Cal [RZ]

NP

▪ **RISEDRONATE (&) CALCIUM CARBONATE**

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

6306

Corticosteroid-induced osteoporosis

Clinical criteria:

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6325

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

6319

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28

8899J

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	5	..	35.49	36.74	Acris Combi [AF]

NP

Other drugs affecting bone structure and mineralization

▪ **CALCITRIOL**

Authority required (STREAMLINED)

5401

Hypocalcaemia

Clinical criteria:

- The condition must be due to renal disease.

Authority required (STREAMLINED)

5255

Hypoparathyroidism

Authority required (STREAMLINED)

5089

Hypophosphataemic rickets

Authority required (STREAMLINED)

5114

Vitamin D-resistant rickets

Authority required (STREAMLINED)**5402**

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

calcitriol 0.25 microgram capsule, 100

2502Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	27.60	28.85	^a APO-Calcitriol [TX]	^a Calciprox [ER]
						^a Calcitriol AN [EA]	^a CALITROL [ED]
						^a Kosteo [RW]	^a Sical [AF]
			^B 2.29	29.89	28.85	^a Rocaltrol [RO]	

■ DENOSUMAB

Note Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

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.

Authority required (STREAMLINED)**4504**

Giant cell tumour of bone

Clinical criteria:

- Patient must be one in whom surgical resection is not feasible; OR
- Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.

Population criteria:

- Patient must be an adult; OR
- Patient must be a skeletally mature adolescent.

denosumab 120 mg/1.7 mL injection, 1.7 mL vial

10061M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	502.06	40.30	Xgeva [AN]

■ DENOSUMAB**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.

Authority required (STREAMLINED)**4158**

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

Authority required (STREAMLINED)**4150**

Bone metastases

Clinical criteria:

- The condition must be due to castration-resistant prostate cancer.

denosumab 120 mg/1.7 mL injection, 1.7 mL vial

5110Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	502.06	40.30	Xgeva [AN]

■ DENOSUMAB

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)**6548**

Osteoporosis

Population criteria:

- Patient must be aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)**6524**

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

denosumab 60 mg/mL injection, 1 mL syringe

5457F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	271.88	40.30	Prolia [AN]

■ RALOXIFENE

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)**6314**

Established post-menopausal osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

raloxifene hydrochloride 60 mg tablet, 28

8363E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	40.89	40.30	^a APO-Raloxifene [TX] ^a Evista [LY] ^a RALOVISTA [RF] ^a Raloxifene AN [EA]	^a Evifyne [EL] ^a Fixta 60 [DO] ^a Raloxifene AMNEAL [ED] ^a Raloxifene GH [GQ]

■ TERIPARATIDE

Note No 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 established osteoporosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

Clinical criteria:

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised agent, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum

requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

Note Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

Authority required

Severe established osteoporosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

Note Up to a maximum of 18 pens will be reimbursed through the PBS.

teriparatide 250 microgram/mL injection, 2.4 mL pen device

9411H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	412.19	40.30	Forteo [LY]

NERVOUS SYSTEM

ANALGESICS

OPIOIDS

Natural opium alkaloids

CODEINE

codeine phosphate hemihydrate 30 mg tablet, 20

1214X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	20.06	21.31	Aspen Pharma Pty Ltd [QA]

NP

CODEINE

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

codeine phosphate hemihydrate 30 mg tablet, 20

5063L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	20.06	21.31	Aspen Pharma Pty Ltd [QA]

DP

HYDROMORPHONE

Caution The risk of drug dependence is high.

hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules

8420E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	25.42	26.67	^a Dilaudid [MF]	^a HYDROMORPHONE JUNO [JU]

NP

hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

8421F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	29.03	30.28	^a Dilaudid-HP [MF]	^a HYDROMORPHONE JUNO-HP [JU]

NP

HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- severe disabling pain associated with proven malignant neoplasia; or
- chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Restricted benefit

Severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

hydromorphone hydrochloride 2 mg tablet, 20

8541M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	21.18	22.43	Dilaudid [MF]

hydromorphone hydrochloride 1 mg/mL oral liquid, 200 mL

11467M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	45.88	40.30	Dilaudid [MF]

hydromorphone hydrochloride 8 mg tablet, 20

8543P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	31.86	33.11	Dilaudid [MF]

hydromorphone hydrochloride 4 mg tablet, 20

8542N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.45	24.70	Dilaudid [MF]

■ **HYDROMORPHONE**

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

hydromorphone hydrochloride 2 mg tablet, 20

5115F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	21.18	22.43	Dilaudid [MF]

hydromorphone hydrochloride 1 mg/mL oral liquid, 200 mL

11479E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	45.88	40.30	Dilaudid [MF]

hydromorphone hydrochloride 8 mg tablet, 20

5117H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	31.86	33.11	Dilaudid [MF]

hydromorphone hydrochloride 4 mg tablet, 20

5116G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	23.45	24.70	Dilaudid [MF]

■ **HYDROMORPHONE**

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

hydromorphone hydrochloride 16 mg modified release tablet, 14

9407D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	46.43	40.30	Jurnista [JC]

hydromorphone hydrochloride 32 mg modified release tablet, 14

9408E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	73.35	40.30	Jurnista [JC]

hydromorphone hydrochloride 4 mg modified release tablet, 14

9299K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	30.00	31.25	Jurnista [JC]

hydromorphone hydrochloride 8 mg modified release tablet, 14

9406C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	33.86	35.11	Jurnista [JC]

hydromorphone hydrochloride 64 mg modified release tablet, 14

9409F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	118.15	40.30	Jurnista [JC]

■ MORPHINE

Caution The risk of drug dependence is high.

morphine tartrate 120 mg/1.5 mL injection, 5 x 1.5 mL ampoules

1607N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	43.23	40.30	Hospira Pty Limited [PF]

morphine hydrochloride trihydrate 100 mg/5 mL injection, 5 x 5 mL ampoules

10878M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	41.47	40.30	Morphine Juno [JU]

morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

1645N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	22.31	23.56	^a Hospira Pty Limited [PF]	^a MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]

morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules

10874H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	24.27	25.52	Morphine Juno [JU]

morphine hydrochloride trihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules

10869C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	30.72	31.97	Morphine Juno [JU]

morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

1647Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	24.41	25.66	^a Hospira Pty Limited [PF]	^a MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]

■ MORPHINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

5169C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	22.31	23.56	^a Hospira Pty Limited [PF]	^a MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]

morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules

10858L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	24.27	25.52	Morphine Juno [JU]

morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

5170D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	24.41	25.66	^a Hospira Pty Limited [PF]	^a MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]

■ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules

1644M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	20.91	22.16	^a Hospira Pty Limited [PF]	^a MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ]

morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules

10864T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	..	..	20.91	22.16	^a Morphine Juno [JU]

■ MORPHINE

Caution The risk of drug dependence is high.

Authority required

Chronic severe disabling pain

Clinical criteria:

- The condition must be due to cancer, **AND**
- The condition must be unresponsive to non-opioid analgesics.

morphine sulfate pentahydrate 200 mg modified release granules, 28 sachets

8454Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	155.15	40.30	MS Contin Suspension 200 mg [MF]

morphine sulfate pentahydrate 200 mg modified release tablet, 28

8453X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	117.07	40.30	MS Contin [MF]

■ MORPHINE

Caution The risk of drug dependence is high.

Restricted benefit

Severe disabling pain

Clinical criteria:

- The condition must be due to cancer, **AND**
- The condition must be unresponsive to non-opioid analgesics.

morphine sulfate pentahydrate 20 mg tablet, 20

8670H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	19.92	21.17	Sevredol [MF]

morphine sulfate pentahydrate 10 mg tablet, 20

8669G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	19.10	20.35	Sevredol [MF]

■ MORPHINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Note Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules

5168B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	20.91	22.16	^a Hospira Pty Limited [PF]	^a MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ]

morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules

10863R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	20.91	22.16	^a Morphine Juno [JU]

■ MORPHINE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- severe disabling pain associated with proven malignant neoplasia; or
- chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Restricted benefit

Severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

morphine sulfate pentahydrate 30 mg tablet, 20

1646P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	18.85	20.10	Anamorph [RW]

morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

2123R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	26.42	27.67	Ordine 5 [MF]

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL

2124T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	30.01	31.26	Ordine 10 [MF]

morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL

2122Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	24.33	25.58	Ordine 2 [MF]

■ MORPHINE**Caution** The risk of drug dependence is high.**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- chronic severe disabling pain associated with proven malignant neoplasia; or
- chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

morphine sulfate pentahydrate 20 mg modified release capsule, 28

2839K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	28.40	29.65	Kapanol [YN]

morphine sulfate pentahydrate 100 mg modified release tablet, 28

1656E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	72.21	40.30	^a Momex SR 100 [RW]	^a Morphine MR AN [EA]
						^a MORPHINE MR APOTEX [TX]	^a Morphine MR Mylan [AF]
						^a MS Contin [MF]	

morphine sulfate pentahydrate 90 mg modified release capsule, 14

8493B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	42.67	40.30	MS Mono [MF]

morphine sulfate pentahydrate 50 mg modified release capsule, 28

2840L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	44.31	40.30	Kapanol [YN]

morphine sulfate pentahydrate 5 mg modified release tablet, 28

8035X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	21.96	23.21	MS Contin [MF]

morphine sulfate pentahydrate 120 mg modified release capsule, 14

8494C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	55.43	40.30	MS Mono [MF]

morphine sulfate pentahydrate 15 mg modified release tablet, 28

8489T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	27.72	28.97	MS Contin [MF]

morphine sulfate pentahydrate 60 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1655D	1	..	..	55.44	40.30	^a Momex SR 60 [RW]	^a Morphine MR AN [EA]
						^a MORPHINE MR APOTEX [TX]	^a Morphine MR Mylan [AF]
						^a MS Contin [MF]	

morphine sulfate pentahydrate 10 mg modified release capsule, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8349K	1	..	..	24.07	25.32	Kapanol [YN]

morphine sulfate pentahydrate 100 mg modified release granules, 28 sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8306E	1	..	..	84.81	40.30	MS Contin Suspension 100 mg [MF]

morphine sulfate pentahydrate 60 mg modified release granules, 28 sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8305D	1	..	..	69.81	40.30	MS Contin Suspension 60 mg [MF]

morphine sulfate pentahydrate 20 mg modified release granules, 28 sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8490W	1	..	..	61.10	40.30	MS Contin Suspension 20 mg [MF]

morphine sulfate pentahydrate 30 mg modified release capsule, 14

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8491X	1	..	..	27.71	28.96	MS Mono [MF]

morphine sulfate pentahydrate 100 mg modified release capsule, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2841M	1	..	..	70.35	40.30	Kapanol [YN]

morphine sulfate pentahydrate 60 mg modified release capsule, 14

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8492Y	1	..	..	37.84	39.09	MS Mono [MF]

morphine sulfate pentahydrate 30 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1654C	1	..	..	37.86	39.11	^a Momex SR 30 [RW]	^a Morphine MR AN [EA]
						^a MORPHINE MR APOTEX [TX]	^a Morphine MR Mylan [AF]
						^a MS Contin [MF]	

morphine sulfate pentahydrate 10 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1653B	1	..	..	24.08	25.33	^a Momex SR 10 [RW]	^a Morphine MR AN [EA]
						^a MORPHINE MR APOTEX [TX]	^a Morphine MR Mylan [AF]
						^a MS Contin [MF]	

morphine sulfate pentahydrate 30 mg modified release granules, 28 sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8146R	1	..	..	62.72	40.30	MS Contin Suspension 30 mg [MF]

■ MORPHINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

morphine sulfate pentahydrate 30 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5163R	1	..	..	18.85	20.10	Anamorph [RW]

morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5238Q	1	..	..	26.42	27.67	Ordine 5 [MF]

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL

5239R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	30.01	31.26	Ordine 10 [MF]

morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL

5237P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	24.33	25.58	Ordine 2 [MF]

■ OXYCODONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Restricted benefit

Severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

oxycodone hydrochloride 20 mg capsule, 20

8502L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	22.63	23.88	^a Oxycodone BNM [LI]	^a OxyNorm [MF]

oxycodone hydrochloride 5 mg tablet, 20

2622B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.54	17.79	^a Endone [QA]	^a Mayne Pharma Oxycodone IR [YN]
						^a Oxycodone Aspen [FM]	

oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL

8644Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	27.83	29.08	OxyNorm Liquid 1mg/mL [MF]

oxycodone 30 mg suppository, 12

2481N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	46.94	40.30	Proladone [FF]

oxycodone hydrochloride 5 mg capsule, 20

8464L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.91	18.16	^a Oxycodone BNM [LI]	^a OxyNorm [MF]

oxycodone hydrochloride 10 mg capsule, 20

8501K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	19.19	20.44	^a Oxycodone BNM [LI]	^a OxyNorm [MF]

■ OXYCODONE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

oxycodone hydrochloride 5 mg tablet, 20

5195K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	16.54	17.79	^a Endone [QA]	^a Mayne Pharma Oxycodone IR [YN]
						^a Oxycodone Aspen [FM]	

oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL

5190E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	27.83	29.08	OxyNorm Liquid 1mg/mL [MF]

oxycodone 30 mg suppository, 12

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5194J	1	..	..	46.94	40.30	Proladone [FF]

oxycodone hydrochloride 5 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5191F	1	..	..	16.91	18.16	^a Oxycodone BNM [LI]	^a OxyNorm [MF]

oxycodone hydrochloride 10 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5197M	1	..	..	19.19	20.44	^a Oxycodone BNM [LI]	^a OxyNorm [MF]

■ OXYCODONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note OxyContin and Novacodone modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

oxycodone hydrochloride 80 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8388L	1	..	..	70.64	40.30	^a Novacodone [HX] ^a OxyContin [MF]	^a Oxycodone Sandoz [SZ]

oxycodone hydrochloride 10 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8385H	1	..	..	25.59	26.84	^a Novacodone [HX] ^a OxyContin [MF]	^a Oxycodone Sandoz [SZ]

oxycodone hydrochloride 20 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8386J	1	..	..	34.07	35.32	^a Novacodone [HX] ^a OxyContin [MF]	^a Oxycodone Sandoz [SZ]

oxycodone hydrochloride 40 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
8387K	1	..	..	48.80	40.30	^a Novacodone [HX] ^a OxyContin [MF]	^a Oxycodone Sandoz [SZ]

■ OXYCODONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

oxycodone hydrochloride 15 mg modified release tablet, 28

9399Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	33.83	35.08	OxyContin [MF]

oxycodone hydrochloride 30 mg modified release tablet, 28

9400R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	47.41	40.30	OxyContin [MF]

■ OXYCODONE + NALOXONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28

10757E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	37.67	38.92	Targin 15/7.5mg [MF]

oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg modified release tablet, 28

8935G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	47.81	40.30	Targin 20/10mg [MF]

oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28

11102H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	80.21	40.30	Targin 60/30 [MF]

oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg modified release tablet, 28

10776E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	24.45	25.70	Targin 2.5/1.25 mg [MF]

oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg modified release tablet, 28

10758F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	53.96	40.30	Targin 30/15 mg [MF]

oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg modified release tablet, 28

8934F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	33.32	34.57	Targin 10/5mg [MF]

oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg modified release tablet, 28

8000C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	32.19	33.44	Targin 5/2.5mg [MF]

oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28

11111T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	94.85	40.30	Targin 80/40 [MF]

oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg modified release tablet, 28

8936H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	72.91	40.30	Targin 40/20mg [MF]

Phenylpiperidine derivatives

■ FENTANYL

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

fentanyl 12 microgram/hour patch, 5

5265D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.05	24.30	^a Denpax [AF]

fentanyl 12 microgram/hour patch, 5

5437E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	23.05	24.30	^a Dutran 12 [EA]	^a Fenpatch 12 [ZP]

fentanyl 12 microgram/hour patch, 5

8878G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	23.05	24.30	^a APO-Fentanyl [TX] ^a Fentanyl Sandoz [SZ]	^a Durogesic 12 [JC]

■ FENTANYL

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

fentanyl 25 microgram/hour patch, 5

5277R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	25.35	26.60	^a Denpax [AF]

fentanyl 25 microgram/hour patch, 5

5438F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	25.35	26.60	^a Dutran 25 [EA]	^a Fenpatch 25 [ZP]

fentanyl 25 microgram/hour patch, 5

8891Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	25.35	26.60	^a APO-Fentanyl [TX] ^a Fentanyl Sandoz [SZ]	^a Durogesic 25 [JC]

■ FENTANYL

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

fentanyl 50 microgram/hour patch, 5

5278T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	34.37	35.62	^a Denpax [AF]

fentanyl 50 microgram/hour patch, 5

5439G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	34.37	35.62	^a Dutran 50 [EA]	^a Fenpatch 50 [ZP]

fentanyl 50 microgram/hour patch, 5

8892B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	34.37	35.62	^a APO-Fentanyl [TX] ^a Fentanyl Sandoz [SZ]	^a Durogesic 50 [JC]

■ FENTANYL

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

fentanyl 75 microgram/hour patch, 5

5279W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	41.70	40.30	^a Denpax [AF]

fentanyl 75 microgram/hour patch, 5

5440H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	41.70	40.30	^a Dutran 75 [EA]	^a Fenpatch 75 [ZP]

fentanyl 75 microgram/hour patch, 5

8893C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	41.70	40.30	^a APO-Fentanyl [TX] ^a Fentanyl Sandoz [SZ]	^a Durogesic 75 [JC]

■ FENTANYL

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

fentanyl 100 microgram/hour patch, 5

5280X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	48.22	40.30	^a Denpax [AF]

fentanyl 100 microgram/hour patch, 5

5441J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	48.22	40.30	^a Dutran 100 [EA]	^a Fenpatch 100 [ZP]

fentanyl 100 microgram/hour patch, 5

8894D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	48.22	40.30	^a APO-Fentanyl [TX] ^a Fentanyl Sandoz [SZ]	^a Durogesic 100 [JC]

Diphenylpropylamine derivatives

■ METHADONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

1606M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	50.27	40.30	Physeptone [QA]

methadone hydrochloride 10 mg tablet, 20

1609Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	19.89	21.14	Physeptone [QA]

Oripavine derivatives

■ BUPRENORPHINE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

buprenorphine 30 microgram/hour patch, 2

10755C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	59.76	40.30	Norspan [MF]

buprenorphine 20 microgram/hour patch, 2

8867Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	48.47	40.30	^a Bupredermal [TX] ^a Norspan [MF]	^a Buprenorphine Sandoz [SZ]

buprenorphine 5 microgram/hour patch, 2

8865N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	26.78	28.03	^a Bupredermal [TX] ^a Norspan [MF]	^a Buprenorphine Sandoz [SZ]

buprenorphine 40 microgram/hour patch, 2

10746N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	71.05	40.30	Norspan [MF]

buprenorphine 10 microgram/hour patch, 2

8866P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	36.55	37.80	^a Bupredermal [TX] ^a Norspan [MF]	^a Buprenorphine Sandoz [SZ]

buprenorphine 15 microgram/hour patch, 2

10770W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	42.50	40.30	^a Buprenorphine Sandoz [SZ]	^a Norspan [MF]

buprenorphine 25 microgram/hour patch, 2

10756D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	54.11	40.30	Norspan [MF]

Opioids in combination with non-opioid analgesics

■ **PARACETAMOL + CODEINE**

paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

3316M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.83	14.08	^a APO- Paracetamol/Codeine 500/30 [TX] ^a Codapane Forte 500/30 [AL] ^a Paracetamol/Codeine GH 500/30 [GQ]	^a Codalgin Forte [FM] ^a Comfarol Forte [SZ] ^a Prodeine Forte [AV]
			^B 2.10	14.93	14.08	^a Panadeine Forte [SW]	

■ **PARACETAMOL + CODEINE**

Note Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of codeine phosphate with paracetamol.

paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

1215Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.83	14.08	^a APO- Paracetamol/Codeine 500/30 [TX] ^a Codapane Forte 500/30 [AL]	^a Codalgin Forte [FM] ^a Comfarol Forte [SZ]

^a Paracetamol/Codeine GH
500/30 [GQ]^a Prodeine Forte [AV]^B2.10

14.93

14.08

^a Panadeine Forte [SW]■ **PARACETAMOL + CODEINE****Note** Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months.**Authority required**

Severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

8785J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	..	..	*15.52	16.77	^a APO- Paracetamol/Codeine 500/30 [TX]	^a Codalgin Forte [FM]
						^a Codapane Forte 500/30 [AL]	^a Comfarol Forte [SZ]
						^a Paracetamol/Codeine GH 500/30 [GQ]	^a Prodeine Forte [AV]
			^B 6.30	*21.82	16.77	^a Panadeine Forte [SW]	

Other opioids■ **TAPENTADOL****Caution** The risk of drug dependence is high.**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

tapentadol 100 mg modified release tablet, 28

10094G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	33.88	35.13	Palexia SR [CS]

tapentadol 250 mg modified release tablet, 28

10092E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	53.77	40.30	Palexia SR [CS]

tapentadol 150 mg modified release tablet, 28

10100N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	41.44	40.30	Palexia SR [CS]

tapentadol 50 mg modified release tablet, 28

10096J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	26.01	27.26	Palexia SR [CS]

tapentadol 200 mg modified release tablet, 28

10091D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	48.11	40.30	Palexia SR [CS]

■ **TRAMADOL****Restricted benefit**

Pain

Clinical criteria:

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

tramadol hydrochloride 100 mg/mL oral liquid, 10 mL

5150C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	±1	..	..	17.82	19.07	Tramal [CS]

■ TRAMADOL

Restricted benefit

Acute pain

Clinical criteria:

- The treatment must be for the short-term.

tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules

5231H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	14.33	15.58	^a Tramadol ACT [JO] ^a Tramadol Sandoz [SZ]	^a Tramadol AN [JU] ^a Tramal 100 [CS]

■ TRAMADOL

Note Authorities for increased maximum quantities and/or repeats will be granted only for severe disabling pain not responding to non-opioid analgesics.

Restricted benefit

Pain

Clinical criteria:

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

tramadol hydrochloride 50 mg modified release tablet, 20

2527B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	14.63	15.88	Tramal SR 50 [CS]

tramadol hydrochloride 100 mg modified release tablet, 20

8523N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	13.89	15.14	^a APO-Tramadol SR [TX] ^a Lodam SR 100 [ZP] ^a Tramadol AN SR [EA] ^a Tramadol SR generichealth [GQ] ^a Zydol SR 100 [RW]	^a Chem mart Tramadol SR [CH] ^a Terry White Chemists Tramadol SR [TW] ^a Tramadol Sandoz SR [SZ] ^a Tramedo SR [AL]
			^b 4.49	18.38	15.14	^a Tramal SR 100 [CS]	

tramadol hydrochloride 200 mg modified release tablet, 20

8525Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.42	16.67	^a APO-Tramadol SR [TX] ^a Terry White Chemists Tramadol SR [TW] ^a Tramadol Sandoz SR [SZ] ^a Tramedo SR [AL]	^a Chem mart Tramadol SR [CH] ^a Tramadol AN SR [EA] ^a Tramadol SR generichealth [GQ] ^a Zydol SR 200 [RW]
			^b 6.08	21.50	16.67	^a Tramal SR 200 [CS]	

tramadol hydrochloride 150 mg modified release tablet, 20

8524P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.71	15.96	^a APO-Tramadol SR [TX] ^a Lodam SR 150 [ZP] ^a Tramadol AN SR [EA] ^a Tramadol SR generichealth [GQ] ^a Zydol SR 150 [RW]	^a Chem mart Tramadol SR [CH] ^a Terry White Chemists Tramadol SR [TW] ^a Tramadol Sandoz SR [SZ] ^a Tramedo SR [AL]
			^b 5.37	20.08	15.96	^a Tramal SR 150 [CS]	

tramadol hydrochloride 100 mg/mL oral liquid, 10 mL

8843K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	17.82	19.07	Tramal [CS]

■ TRAMADOL

Restricted benefit

Acute pain

Clinical criteria:

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

Restricted benefit

Chronic pain

Treatment Phase: Dose titration

Clinical criteria:

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

tramadol hydrochloride 50 mg capsule, 20

5232J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.48	14.73	^a APO-Tramadol [TX] ^a Terry White Chemists Tramadol [TW] ^a Tramadol AN [EA] ^a Tramadol SCP [CR] ^a Zydol [RW]	^a Chem mart Tramadol [CH] ^a Tramadol AMNEAL [EF] ^a Tramadol Sandoz [SZ] ^a Tramedo [AF]
			^B 2.42	15.90	14.73	^a Tramal [CS]	

■ TRAMADOL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Acute pain

Clinical criteria:

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

tramadol hydrochloride 50 mg capsule, 20

8455B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	13.48	14.73	^a APO-Tramadol [TX] ^a Terry White Chemists Tramadol [TW] ^a Tramadol AN [EA] ^a Tramadol SCP [CR] ^a Zydol [RW]	^a Chem mart Tramadol [CH] ^a Tramadol AMNEAL [EF] ^a Tramadol Sandoz [SZ] ^a Tramedo [AF]
			^B 2.42	15.90	14.73	^a Tramal [CS]	

■ TRAMADOL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Acute pain

Clinical criteria:

- The treatment must be for the short-term.

tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules

8582Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.33	15.58	^a Tramadol ACT [JO] ^a Tramadol Sandoz [SZ]	^a Tramadol AN [JU] ^a Tramal 100 [CS]

■ TRAMADOL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Chronic pain

Treatment Phase: Dose titration

Clinical criteria:

- The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

tramadol hydrochloride 50 mg capsule, 20

8611F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	13.48	14.73	^a APO-Tramadol [TX] ^a Terry White Chemists Tramadol [TW] ^a Tramadol AN [EA] ^a Tramadol SCP [CR] ^a Zydol [RW]	^a Chem mart Tramadol [CH] ^a Tramadol AMNEAL [EF] ^a Tramadol Sandoz [SZ] ^a Tramedo [AF]
			^B 2.42	15.90	14.73	^a Tramal [CS]	

OTHER ANALGESICS AND ANTIPYRETICS*Salicylic acid and derivatives***■ ASPIRIN****Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

aspirin 300 mg effervescent tablet, 96

1010E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	13.00	14.25	Solprin [RC]

■ ASPIRIN**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

aspirin 300 mg effervescent tablet, 96

5018D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	13.00	14.25	Solprin [RC]

*Anilides***■ PARACETAMOL****Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

paracetamol 500 mg tablet, 100

1746X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	13.13	14.38	^a APO-Paracetamol [TX] ^a Mendelev Paracetamol [HX] ^a Paracetamol Generic Health [GQ] ^a Paralgin [OW] ^a PHARMACY CARE PARACETAMOL [SI]	^a Febridol [EA] ^a Panamax [SW] ^a Paracetamol (Sandoz) [SZ] ^a Parapane [AF]

paracetamol 240 mg/5 mL oral liquid, 200 mL

1770E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	15.18	16.43	Panamax 240 Elixir [SW]

paracetamol 120 mg/5 mL oral liquid, 100 mL

1747Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	14.05	15.30	Panamax [SW]

■ PARACETAMOL**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

paracetamol 500 mg tablet, 100

5196L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.13	14.38	^a APO-Paracetamol [TX] ^a Mendelev Paracetamol [HX] ^a Paracetamol Generic Health [GQ] ^a Paralgin [OW] ^a PHARMACY CARE PARACETAMOL [SI]	^a Febridol [EA] ^a Panamax [SW] ^a Paracetamol (Sandoz) [SZ] ^a Parapane [AF]

paracetamol 240 mg/5 mL oral liquid, 200 mL

3349G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	±1	..	..	15.18	16.43	Panamax 240 Elixir [SW]

paracetamol 120 mg/5 mL oral liquid, 100 mL

3348F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	±1	..	..	14.05	15.30	Panamax [SW]

■ PARACETAMOL**Restricted benefit**

Chronic arthropathies

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

paracetamol 500 mg tablet, 100

5224Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	3	..	..	*16.42	17.67	^a APO-Paracetamol [TX] ^a Mendelev Paracetamol [HX] ^a Paracetamol Generic Health [GQ] ^a Paralgin [OW]	^a Febridol [EA] ^a Panamax [SW] ^a Paracetamol (Sandoz) [SZ] ^a Parapane [AF]

^a PHARMACY CARE
PARACETAMOL [SI]

■ PARACETAMOL

Restricted benefit

Chronic arthropathies

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

paracetamol 500 mg tablet, 100

8784H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	4	..	*16.42	17.67	^a APO-Paracetamol [TX] ^a Mendelev Paracetamol [HX] ^a Paracetamol Generic Health [GQ] ^a Paralgin [OW] ^a PHARMACY CARE PARACETAMOL [SI]	^a Febridol [EA] ^a Panamax [SW] ^a Paracetamol (Sandoz) [SZ] ^a Parapane [AF]

■ PARACETAMOL

Note Pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 96 and pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 192 are equivalent for the purposes of substitution.

Restricted benefit

Persistent pain

Clinical criteria:

- The condition must be associated with osteoarthritis.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

paracetamol 665 mg modified release tablet, 192

10797G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.94	20.19	^a Osteomol 665 Paracetamol [CR]

paracetamol 665 mg modified release tablet, 96

8814X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.95	20.20	^a APOHEALTH Osteo Relief Paracetamol 665 mg [TX]	^a Osteomol 665 Paracetamol [CR]

Other analgesics and antipyretics

■ PREGABALIN

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.

Authority required (STREAMLINED)

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Neuropathic pain

Clinical criteria:

- The condition must be refractory to treatment with other drugs.

pregabalin 25 mg capsule, 56

2348N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.45	22.70	^a APO-Pregabalin [TX] ^a BTC PREGABALIN [JB] ^a Lyrica [PF] ^a Neuroccord [CR] ^a Pregabalin APOTEX [GX] ^a Pregabalin GH [GQ] ^a Pregabalin-Teva [TB]	^a Blooms The Chemist Pregabalin [IB] ^a LYPRALIN [RW] ^a Lyzalon [AF] ^a Pregabalin AMNEAL [EA] ^a PREGABALIN-DRLA [RZ] ^a Pregabalin Sandoz [SZ]

pregabalin 300 mg capsule, 56

2363J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	61.96	40.30	^a APO-Pregabalin [TX] ^a BTC PREGABALIN [JB] ^a Lyrica [PF] ^a Neuroccord [CR] ^a Pregabalin APOTEX [GX] ^a Pregabalin GH [GQ] ^a Pregabalin-Teva [TB]	^a Blooms The Chemist Pregabalin [IB] ^a LYPRALIN [RW] ^a Lyzalon [AF] ^a Pregabalin AMNEAL [EA] ^a PREGABALIN-DRLA [RZ] ^a Pregabalin Sandoz [SZ]

pregabalin 150 mg capsule, 56

2355Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	45.32	40.30	^a APO-Pregabalin [TX]	^a Blooms The Chemist Pregabalin [IB]
						^a BTC PREGABALIN [JB]	^a LYPRALIN [RW]
						^a Lyrica [PF]	^a Lyzalon [AF]
						^a Neuroccord [CR]	^a Pregabalin AMNEAL [EA]
						^a Pregabalin APOTEX [GX]	^a PREGABALIN-DRLA [RZ]
						^a Pregabalin GH [GQ]	^a Pregabalin Sandoz [SZ]
						^a Pregabalin-Teva [TB]	

pregabalin 75 mg capsule, 56

2335X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.53	34.78	^a APO-Pregabalin [TX]	^a Blooms The Chemist Pregabalin [IB]
						^a BTC PREGABALIN [JB]	^a LYPRALIN [RW]
						^a Lyrica [PF]	^a Lyzalon [AF]
						^a Neuroccord [CR]	^a Pregabalin AMNEAL [EA]
						^a Pregabalin APOTEX [GX]	^a PREGABALIN-DRLA [RZ]
						^a Pregabalin GH [GQ]	^a Pregabalin Sandoz [SZ]
						^a Pregabalin-Teva [TB]	

ANTIMIGRAINE PREPARATIONS*Selective serotonin (5HT₁) agonists***■ ELETRIPTAN**

Caution Selective serotonin (5HT₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No 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 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.

Restricted benefit

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past.

eletriptan 40 mg tablet, 4

5290K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	26.63	27.88	Relpax [PF]

eletriptan 80 mg tablet, 4

5291L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	26.63	27.88	Relpax [PF]

■ NARATRIPTAN

Caution Selective serotonin (5HT₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No 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 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.

Authority required

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past.

naratriptan 2.5 mg tablet, 2

8298R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	£1.96	*27.21	26.50	Naramig [AS]

■ NARATRIPTAN

Caution Selective serotonin (5HT₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No 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 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.

Authority required

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom adverse events have occurred with other suitable PBS-listed drugs.

Authority required

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions have occurred with other suitable PBS-listed drugs.

Authority required

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions are expected to occur with other suitable PBS-listed drugs.

Authority required

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance.

Authority required

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.

naratriptan 2.5 mg tablet, 2

9734H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*27.21	28.46	Naramig [AS]

▪ **RIZATRIPTAN**

Caution Selective serotonin (5HT₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No 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 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 form rizatriptan wafer 10 mg (as benzoate) and pharmaceutical benefits that have the form rizatriptan tablet (orally disintegrating) 10 mg (as benzoate) are equivalent for the purposes of substitution.

Restricted benefit

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past.

rizatriptan 10 mg orally disintegrating tablet, 2

10551H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.31	22.56	^a APO-Rizatriptan [TX] ^a Rizatriptan AN ODT [EA]	^a RIXALT [RF] ^a Rizatriptan ODT GH [GQ]

rizatriptan 10 mg wafer, 2

9313E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.31	22.56	^a Maxalt [AL]	^a Rizatriptan Wafers-10mg [AF]

▪ **SUMATRIPTAN**

Caution Selective serotonin (5HT₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No 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 Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

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.

Restricted benefit

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past.

SUMATRIPTAN Tablet 50 mg (base) (fast disintegrating), 4

10694W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	^B 4.19	20.83	17.89	^a Imigran FDT [AS]

sumatriptan 50 mg tablet, 2

8144P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*16.65	17.90	^a APO-Sumatriptan [TX] ^a Sumatran [OW]	^a Iptam [AL] ^a Sumatriptan Sandoz [SZ]
			^B 4.20	*20.85	17.90	^a Imigran [LN]	

sumatriptan 50 mg tablet, 4

1849H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.64	17.89	^a APO-Sumatriptan [TX] ^a Pharmacor Sumatriptan 50 [CR] ^a Sumatriptan AN [EA] ^a Sumatriptan Sandoz [SZ]	^a Iptam [AL] ^a Sumatran [OW] ^a Sumatriptan generichealth [GQ]
			^B 4.19	20.83	17.89	^a Imigran [LN]	

SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2

8885P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	^B 4.20	*20.85	17.90	^a Imigran FDT [AS]

sumatriptan 20 mg/actuation nasal spray, 2 x 1 actuation

8341B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.32	24.57	Imigran [AS]

▪ **ZOLMITRIPTAN**

Caution Selective serotonin (5HT₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No 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 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.

Restricted benefit

Migraine attack

Clinical criteria:

- The condition must have usually failed to respond to analgesics in the past.

zolmitriptan 2.5 mg tablet, 2

8266C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*23.37	24.62	^a APO-Zolmitriptan [TX]	^a Zoltrip [RW]
			^B 2.76	*26.13	24.62	^a Zomig [AP]	

Other antimigraine preparations

▪ **PIZOTIFEN**

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.

pizotifen 500 microgram tablet, 100

3074T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	23.09	24.34	Sandomigran 0.5 [AE]

■ ANTIEPILEPTICS

ANTIEPILEPTICS

Barbiturates and derivatives

■ PHENOBARBITAL (PHENOBARBITONE)

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.

Restricted benefit

Epilepsy

phenobarbital (phenobarbitone) 30 mg tablet, 200

1850J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	..	18.67	19.92	Phenobarb [RW]

phenobarbital (phenobarbitone) sodium 219 mg/mL injection, 5 x 1 mL ampoules

2138M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	34.51	35.76	Fawns and McAllan Proprietary Limited [FM]

■ PRIMIDONE

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.

primidone 250 mg tablet, 200

1939C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	68.38	40.30	Mysoline [LM]

Hydantoin derivatives

■ PHENYTOIN

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.

phenytoin 30 mg/5 mL oral liquid, 500 mL

2692Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	3	..	31.20	32.45	Dilantin [PF]

phenytoin 50 mg chewable tablet, 200

1249R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	43.46	40.30	Dilantin Infatabs [PF]

phenytoin sodium 100 mg capsule, 200

1874P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	31.80	33.05	Dilantin Sodium [PF]

phenytoin sodium 30 mg capsule, 200

1873N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	28.56	29.81	Dilantin Sodium [PF]

Succinimide derivatives

■ ETHOSUXIMIDE

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.

ethosuximide 250 mg/5 mL oral liquid, 200 mL

1414K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	72.07	40.30	Zarontin [IX]

■ ETHOSUXIMIDE

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 form ethosuximide 250 mg capsule, 200 and pharmaceutical benefits that have the form ethosuximide 250 mg capsule, 100 are equivalent for the purposes of substitution.

ethosuximide 250 mg capsule, 100

11703Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*288.93	40.30	^a Zarontin [IX]

ethosuximide 250 mg capsule, 200

1413J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	288.93	40.30	^a Zarontin [IX]

Benzodiazepine derivatives

CLONAZEPAM

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.

Restricted benefit

Epilepsy

clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack

1807D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	22.05	23.30	Rivotril [RO]

CLONAZEPAM

Caution Abuse of clonazepam has been reported. Refer to the current product information.

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.

Authority required

Epilepsy

Clinical criteria:

- The condition must be neurologically proven.

clonazepam 2 mg tablet, 100

1806C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*32.91	34.16	^a Paxam 2 [AF]
			^B 4.60	*37.51	34.16	^a Rivotril [RO]

clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL

1808E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*18.99	20.24	Rivotril [RO]

CLONAZEPAM

Caution Abuse of clonazepam has been reported. Refer to the current product information.

Note Pharmaceutical benefits that have form pack size clonazepam 500 microgram tablet, 100 and clonazepam 500 microgram tablet, 50 are equivalent for the purposes of substitution.

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.

Authority required

Epilepsy

Clinical criteria:

- The condition must be neurologically proven.

clonazepam 500 microgram tablet, 100

1805B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*22.89	24.14	^a Paxam 0.5 [AF]
			^B 3.68	*26.57	24.14	^a Rivotril [RO]

clonazepam 500 microgram tablet, 50

11559J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	2	^B 3.68	*26.55	24.12	^a Rivotril [RO]

■ NITRAZEPAM

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.

Authority required

Myoclonic epilepsy

Authority required

Malignant neoplasia (late stage)

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

nitrazepam 5 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2732T	2	5	..	*14.71	15.96	^a Alodorm [AF]
			^B 2.48	*17.19	15.96	^a Mogadon [IL]

Carboxamide derivatives

■ CARBAMAZEPINE

carbamazepine 100 mg/5 mL oral liquid, 300 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5041H	‡1	..	..	24.46	25.71	Tegretol Liquid [NV]

carbamazepine 200 mg modified release tablet, 200

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5038E	1	..	..	31.53	32.78	Tegretol CR 200 [NV]

carbamazepine 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1724R	2	..	..	*31.13	32.38	^a Carbamazepine Sandoz [SZ]
			^B 2.96	*34.09	32.38	^a Tegretol 200 [NV]

carbamazepine 400 mg modified release tablet, 200

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5037D	1	..	..	49.59	40.30	Tegretol CR 400 [NV]

carbamazepine 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5039F	2	..	..	*23.25	24.50	^a Carbamazepine Sandoz [SZ]
			^B 3.00	*26.25	24.50	^a Tegretol 100 [NV]

■ CARBAMAZEPINE

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.

carbamazepine 100 mg/5 mL oral liquid, 300 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2427R	‡1	5	..	24.46	25.71	Tegretol Liquid [NV]

carbamazepine 200 mg modified release tablet, 200

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2426Q	1	2	..	31.53	32.78	Tegretol CR 200 [NV]

carbamazepine 200 mg tablet, 100

1706T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*31.13	32.38	^a Carbamazepine Sandoz [SZ]
			^B 2.96	*34.09	32.38	^a Tegretol 200 [NV]

carbamazepine 400 mg modified release tablet, 200

2431Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	49.59	40.30	Tegretol CR 400 [NV]

carbamazepine 100 mg tablet, 100

2422L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*23.25	24.50	^a Carbamazepine Sandoz [SZ]
			^B 3.00	*26.25	24.50	^a Tegretol 100 [NV]

■ OXCARBAZEPINE**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.

Authority required (STREAMLINED)**5183**

Seizures

Clinical criteria:

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

oxcarbazepine 150 mg tablet, 100

8584T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	60.10	40.30	Trileptal [NV]

oxcarbazepine 60 mg/mL oral liquid, 250 mL

8588B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*108.73	40.30	Trileptal [NV]

oxcarbazepine 300 mg tablet, 100

8585W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	91.71	40.30	Trileptal [NV]

oxcarbazepine 600 mg tablet, 100

8586X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	145.54	40.30	Trileptal [NV]

Fatty acid derivatives**■ TIAGABINE****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.

Authority required (STREAMLINED)**4928**

Partial epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

tiagabine 5 mg tablet, 50

8221Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*60.37	40.30	Gabitril [TB]

tiagabine 10 mg tablet, 50

8222R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*109.27	40.30	Gabitril [TB]

tiagabine 15 mg tablet, 50

8223T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*152.13	40.30	Gabitril [TB]

■ VALPROATE

Caution There are reports of fatal hepatotoxicity, particularly in children.

There is increasing evidence of dose-related teratogenesis from 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.

valproate sodium 200 mg/5 mL oral liquid, 300 mL

2293Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*39.45	40.30	Epilim Liquid [SW]

valproate sodium 200 mg/5 mL oral liquid, 300 mL

2295T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*39.45	40.30	Epilim Syrup [SW]

valproate sodium 500 mg enteric tablet, 100

2290M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*34.73	35.98	^a Sodium Valproate Sandoz [SZ] ^a Valproate Winthrop EC 500 [WA]	^a Valprease 500 [RW] ^a Valpro EC 500 [AF]
			^b 2.00	*36.73	35.98	^a Epilim EC [SW]	

valproate sodium 200 mg enteric tablet, 100

2289L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*23.23	24.48	^a Sodium Valproate Sandoz [SZ] ^a Valproate Winthrop EC 200 [WA]	^a Valprease 200 [RW] ^a Valpro EC 200 [AF]
			^b 2.00	*25.23	24.48	^a Epilim EC [SW]	

valproate sodium 100 mg tablet, 100

2294R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*33.73	34.98	Epilim [SW]

■ VIGABATRIN

Caution Visual field defects have been reported 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.

Authority required (STREAMLINED)

4929

Epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

vigabatrin 500 mg powder for oral liquid, 60 sachets

2668K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	65.19	40.30	Sabril [SW]

vigabatrin 500 mg tablet, 100

2667J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	94.44	40.30	Sabril [SW]

Other antiepileptics

■ BRIVARACETAM

Authority required (STREAMLINED)

7597

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- The treatment must not be given concomitantly with levetiracetam, except for cross titration.

Population criteria:

- Patient must be aged 16 years or older.

brivaracetam 100 mg tablet, 56

11339T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	160.69	40.30	Briviact [UC]

brivaracetam 25 mg tablet, 56

11328F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	160.69	40.30	Briviact [UC]

brivaracetam 50 mg tablet, 56

11334M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	160.69	40.30	Briviact [UC]

brivaracetam 75 mg tablet, 56

11356Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	160.69	40.30	Briviact [UC]

■ **BRIVARACETAM****Authority required (STREAMLINED)****7618**

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must not be given concomitantly with levetiracetam, except for cross titration.

Population criteria:

- Patient must be aged 16 years or older.

brivaracetam 10 mg/mL oral liquid, 300 mL

11349H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	198.21	40.30	Briviact [UC]

■ **BRIVARACETAM****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.

Authority required (STREAMLINED)**7608**

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The treatment must not be given concomitantly with levetiracetam.

Population criteria:

- Patient must be aged 16 years or older.

brivaracetam 100 mg tablet, 56

11357R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	160.69	40.30	Briviact [UC]

brivaracetam 25 mg tablet, 56

11327E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	160.69	40.30	Briviact [UC]

brivaracetam 50 mg tablet, 56

11338R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	160.69	40.30	Briviact [UC]

brivaracetam 75 mg tablet, 56

11350J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	160.69	40.30	Briviact [UC]

■ BRIVARACETAM**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.

Authority required (STREAMLINED)**7596**

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must not be given concomitantly with levetiracetam.

Population criteria:

- Patient must be aged 16 years or older.

brivaracetam 10 mg/mL oral liquid, 300 mL

11358T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	198.21	40.30	Briviact [UC]

■ GABAPENTIN**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.

Authority required (STREAMLINED)**4928**

Partial epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

gabapentin 300 mg capsule, 100

1834M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.98	26.23	^a APO-Gabapentin [TX] ^a Gabapentin AN [EA] ^a Gabapentin Aspen 300 [RW] ^a Gabapentin Sandoz [SZ] ^a GenRx Gabapentin [GX] ^a Nupentin 300 [AF]	^a Gabacor [CR] ^a Gabapentin APOTEX [TY] ^a Gabapentin generichealth [HQ] ^a GAPENTIN [RF] ^a Neurontin [PF]

gabapentin 800 mg tablet, 100

8389M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	50.45	40.30	^a APO-Gabapentin [TX] ^a Gabapentin Aspen 800 [RW] ^a GenRx Gabapentin [GX] ^a Pharmacor Gabapentin 800 [CR]	^a Gabapentin AN [EA] ^a GAPENTIN [RF] ^a Neurontin [PF]

gabapentin 400 mg capsule, 100

1835N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.89	31.14	^a APO-Gabapentin [TX] ^a Gabapentin AN [EA] ^a Gabapentin Aspen 400 [RW] ^a Gabapentin Sandoz [SZ] ^a GenRx Gabapentin [GX] ^a Nupentin 400 [AF]	^a Gabacor [CR] ^a Gabapentin APOTEX [TY] ^a Gabapentin generichealth [HQ] ^a GAPENTIN [RF] ^a Neurontin [PF]

gabapentin 100 mg capsule, 100

8505P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.52	16.77	^a APO-Gabapentin [TX] ^a Gabapentin APOTEX [TY] ^a GAPENTIN [RF] ^a Nupentin 100 [AF]	^a Gabacor [CR] ^a Gabapentin Aspen 100 [RW] ^a Neurontin [PF]

gabapentin 600 mg tablet, 100

8559L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	40.70	40.30	^a APO-Gabapentin [TX] ^a Gabapentin Aspen 600 [RW] ^a GenRx Gabapentin [GX] ^a Pharmacor Gabapentin 600 [CR]	^a Gabapentin AN [EA] ^a GAPENTIN [RF] ^a Neurontin [PF]

■ LACOSAMIDE**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.

Authority required (STREAMLINED)**8813**

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
- The treatment must be for dose titration purposes.

lacosamide 100 mg tablet, 14

9334G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	50.79	40.30	Vimpat [UC]

lacosamide 50 mg tablet, 14

9333F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	31.13	32.38	Vimpat [UC]

lacosamide 150 mg tablet, 14

9336J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	70.43	40.30	Vimpat [UC]

■ LACOSAMIDE**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.

Authority required (STREAMLINED)**8815**

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

lacosamide 50 mg tablet, 14

10293R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*90.07	40.30	Vimpat [UC]

■ LACOSAMIDE**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.

Authority required (STREAMLINED)**8770**

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Authority required (STREAMLINED)**8815**

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

lacosamide 100 mg tablet, 56

9335H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	168.72	40.30	Vimpat [UC]

■ LACOSAMIDE**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 No increase in the maximum quantity or number of units may be authorised.

Authority required (STREAMLINED)**8770**

Intractable partial epileptic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Authority required (STREAMLINED)**8815**

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

lacosamide 10 mg/mL oral liquid, 200 mL

11694L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±6	5	..	*388.75	40.30	Vimpat [UC]

lacosamide 200 mg tablet, 56

9338L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	330.59	40.30	Vimpat [UC]

lacosamide 150 mg tablet, 56

9337K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	249.24	40.30	Vimpat [UC]

■ LAMOTRIGINE**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.

Authority required (STREAMLINED)**5138**

Epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

lamotrigine 5 mg tablet, 56

8063J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.80	19.05	^a Lamictal [AS]	^a Lamotrigine Aspen 5 [RW]

lamotrigine 25 mg tablet, 56

2848X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.05	18.30	^a APO-Lamotrigine [TX] ^a Lamotrigine AN [EA]	^a LAMITAN [RF] ^a Lamotrigine Aspen 25 [RW]

^a Lamotrigine GH [GQ] ^a Lamotrigine Sandoz [SZ]
^a Logem [AL] ^a Reedos 25 [DO]
^a Sandoz Lamotrigine [HX]
^a Lamictal [AS]

lamotrigine 200 mg tablet, 56

2851C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	37.45	38.70	^a APO-Lamotrigine [TX] ^a Lamotrigine AN [EA] ^a Lamotrigine GH [GQ] ^a Logem [AL] ^a Sandoz Lamotrigine [HX] ^a Lamictal [AS]	^a LAMITAN [RF] ^a Lamotrigine Aspen 200 [RW] ^a Lamotrigine Sandoz [SZ] ^a Reedos 200 [DO]
			^b 1.61	18.66	18.30		

lamotrigine 50 mg tablet, 56

2849Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.76	22.01	^a APO-Lamotrigine [TX] ^a Lamotrigine AN [EA] ^a Lamotrigine GH [GQ] ^a Logem [AL] ^a Sandoz Lamotrigine [HX] ^a Lamictal [AS]	^a LAMITAN [RF] ^a Lamotrigine Aspen 50 [RW] ^a Lamotrigine Sandoz [SZ] ^a Reedos 50 [DO]
			^b 1.44	22.20	22.01		

lamotrigine 100 mg tablet, 56

2850B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	26.93	28.18	^a APO-Lamotrigine [TX] ^a Lamotrigine AN [EA] ^a Lamotrigine GH [GQ] ^a Logem [AL] ^a Sandoz Lamotrigine [HX] ^a Lamictal [AS]	^a LAMITAN [RF] ^a Lamotrigine Aspen 100 [RW] ^a Lamotrigine Sandoz [SZ] ^a Reedos 100 [DO]
			^b 1.51	28.44	28.18		

■ LEVETIRACETAM**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.

Authority required (STREAMLINED)**7603**

Partial epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

levetiracetam 500 mg tablet, 60

8655M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	30.68	31.93	^a APO-Levetiracetam [TX] ^a Kerron 500 [DO] ^a Levactam [ER] ^a Levetiracetam AN [EA] ^a Levetiracetam SZ [SZ]	^a Keppra [UC] ^a Kevtam 500 [AF] ^a Levecetam 500 [RZ] ^a Levetiracetam GH [GQ] ^a Levi 500 [RW]

levetiracetam 1 g tablet, 60

8656N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	43.48	40.30	^a APO-Levetiracetam [TX] ^a Kerron 1000 [DO] ^a Levactam [ER] ^a Levetiracetam AN [EA] ^a Levetiracetam SZ [SZ]	^a Keppra [UC] ^a Kevtam 1000 [AF] ^a Levecetam 1000 [RZ] ^a Levetiracetam GH [GQ] ^a Levi 1000 [RW]

levetiracetam 250 mg tablet, 60

8654L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.01	24.26	^a APO-Levetiracetam [TX] ^a Kerron 250 [DO] ^a Levactam [ER] ^a Levetiracetam AN [EA] ^a Levetiracetam SZ [SZ]	^a Keppra [UC] ^a Kevtam 250 [AF] ^a Levecetam 250 [RZ] ^a Levetiracetam GH [GQ] ^a Levi 250 [RW]

■ LEVETIRACETAM**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.

Authority required (STREAMLINED)

7620

Partial epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of levetiracetam, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

levetiracetam 100 mg/mL oral liquid, 300 mL

9169N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	73.84	40.30	^a APO-Levetiracetam [TX] ^a Kerron [DO]	^a Keppra [UC] ^a Levetiracetam-AFT [AE]

■ PERAMPANEL

Authority required (STREAMLINED)

4656

Intractable partial epileptic seizures

Treatment Phase: Initial

Clinical criteria:

- The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Treatment criteria:

- Must be treated by a neurologist.

perampanel 2 mg tablet, 7

10157N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*52.87	40.30	Fycompa [EI]

■ PERAMPANEL

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.

Authority required (STREAMLINED)

4658

Intractable partial epileptic seizures

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug.

perampanel 12 mg tablet, 28

10159Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	347.72	40.30	Fycompa [EI]

perampanel 4 mg tablet, 28

10162W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	176.97	40.30	Fycompa [EI]

perampanel 6 mg tablet, 28

10163X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	262.11	40.30	Fycompa [EI]

perampanel 8 mg tablet, 28

10160R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	347.72	40.30	Fycompa [EI]

perampanel 10 mg tablet, 28

10151G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	347.72	40.30	Fycompa [EI]

■ PERAMPANEL

Note No applications for increased maximum quantities will be authorised.

Authority required (STREAMLINED)

7815

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs, **AND**
- The treatment must be in combination with at least one PBS-subsidised anti-epileptic drug, **AND**
- The treatment must be for dose titration purposes.

Population criteria:

- Patient must be aged 12 years or older.

perampanel 2 mg tablet, 7

11436X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*52.87	40.30	Fycompa [EI]

▪ **PERAMPANEL**

Note No applications for increased maximum quantities will be authorised.

Note Special Pricing Arrangements apply.

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.

Authority required (STREAMLINED)

7789

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Population criteria:

- Patient must be aged 12 years or older.

perampanel 12 mg tablet, 28

11409L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	347.72	40.30	Fycompa [EI]

perampanel 4 mg tablet, 28

11418Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	176.97	40.30	Fycompa [EI]

perampanel 6 mg tablet, 28

11407J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	262.11	40.30	Fycompa [EI]

perampanel 8 mg tablet, 28

11429M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	347.72	40.30	Fycompa [EI]

perampanel 10 mg tablet, 28

11428L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	347.72	40.30	Fycompa [EI]

▪ **SULTHIAME**

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.

sulthiame 200 mg tablet, 200

2100M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	158.97	40.30	Ospolot [FF]

sulthiame 50 mg tablet, 200

2099L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	67.64	40.30	Ospolot [FF]

▪ **TOPIRAMATE**

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.

Authority required (STREAMLINED)

5516

Seizures

Clinical criteria:

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

topiramate 200 mg tablet, 60

8166T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	40.87	40.30	^a APO-Topiramate [TX] ^a RBX Topiramate [RA] ^a Topamax [JC] ^a Topiramate Sandoz [SZ]	^a Epiramax 200 [RW] ^a Tamate [AF] ^a Topiramate AN [EA]

topiramate 100 mg tablet, 60

8165R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.97	30.22	^a APO-Topiramate [TX] ^a RBX Topiramate [RA] ^a Topamax [JC] ^a Topiramate Sandoz [SZ]	^a Epiramax 100 [RW] ^a Tamate [AF] ^a Topiramate AN [EA]

■ TOPIRAMATE

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.

Authority required (STREAMLINED)

5173

Seizures

Clinical criteria:

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of topiramate.

topiramate 50 mg capsule, 60

8520K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	22.58	23.83	Topamax Sprinkle [JC]

topiramate 25 mg capsule, 60

8372P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	18.14	19.39	Topamax Sprinkle [JC]

topiramate 15 mg capsule, 60

8371N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.57	20.82	Topamax Sprinkle [JC]

■ TOPIRAMATE

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.

Authority required (STREAMLINED)

5516

Seizures

Clinical criteria:

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

Authority required (STREAMLINED)

5325

Migraine

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

topiramate 50 mg tablet, 60

8164Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.60	23.85	^a APO-Topiramate [TX] ^a RBX Topiramate [RA] ^a Topamax [JC] ^a Topiramate Sandoz [SZ]	^a Epiramax 50 [RW] ^a Tamate [AF] ^a Topiramate AN [EA]

topiramate 25 mg tablet, 60

8163P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.25	19.50	^a APO-Topiramate [TX] ^a RBX Topiramate [RA] ^a Topamax [JC] ^a Topiramate Sandoz [SZ]	^a Epiramax 25 [RW] ^a Tamate [AF] ^a Topiramate AN [EA]

■ ZONISAMIDE

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.

Authority required (STREAMLINED)

4928

Partial epileptic seizures

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

zonisamide 25 mg capsule, 56

9388D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.84	24.09	^a APO-Zonisamide [TX]	^a Zonegran [EI]

zonisamide 100 mg capsule, 56

9390F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*74.63	40.30	^a APO-Zonisamide [TX]	^a Zonegran [EI]

zonisamide 50 mg capsule, 56

9389E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	30.43	31.68	^a APO-Zonisamide [TX]	^a Zonegran [EI]

■ ANTI-PARKINSON DRUGS

ANTICHOLINERGIC AGENTS

Tertiary amines

■ BIPERIDEN

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.

biperiden hydrochloride 2 mg tablet, 100

2544X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*21.71	22.96	Akineton [GH]

■ TRIHEXYPHENIDYL (BENZHEXOL)

trihexyphenidyl (benzhexol) hydrochloride 5 mg tablet, 200

1110K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	22.94	24.19	Artane [RW]

trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11209J	1	2	..	18.11	19.36	Artane [RW]

NP

*Ethers of tropine or tropine derivatives***■ BENZATROPINE****benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11249C	1	..	..	116.38	40.30	Benzatropine Injection [FF]

DP

benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11255J	1	..	..	116.38	40.30	Benzatropine Injection [FF]

NP

benzatropine mesilate 2 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2362H	1	2	..	17.63	18.88	Benztrop [FF]

NP

DOPAMINERGIC AGENTS*Dopa and dopa derivatives***■ LEVODOPA + BENSERAZIDE****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.

levodopa 200 mg + benserazide 50 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2226E	1	5	..	43.23	40.30	Madopar [RO]

NP

levodopa 50 mg + benserazide 12.5 mg dispersible tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8218M	1	5	..	23.19	24.44	Madopar Rapid 62.5 [RO]

NP

levodopa 100 mg + benserazide 25 mg modified release capsule, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2231K	1	5	..	36.73	37.98	Madopar HBS [RO]

NP

levodopa 100 mg + benserazide 25 mg dispersible tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8219N	1	5	..	34.44	35.69	Madopar Rapid 125 [RO]

NP

levodopa 100 mg + benserazide 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2229H	1	5	..	34.44	35.69	Madopar 125 [RO]

NP

levodopa 100 mg + benserazide 25 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2225D	1	5	..	34.44	35.69	Madopar 125 [RO]

NP

levodopa 50 mg + benserazide 12.5 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2227F	1	5	..	23.19	24.44	Madopar 62.5 [RO]

NP

levodopa 200 mg + benserazide 50 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2228G	1	5	..	43.23	40.30	Madopar [RO]

NP

■ LEVODOPA + CARBIDOPA**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.

levodopa 250 mg + carbidopa 25 mg tablet, 100

11655K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	75.45	40.30	^a Carbidopa and Levodopa Tablets, USP [DZ]

levodopa 250 mg + carbidopa 25 mg tablet, 100

1245M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	45.65	40.30	^a Sinemet [MK]

levodopa 100 mg + carbidopa 25 mg tablet, 100

1242J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	39.19	40.30	^a Kinson [AF]
			^B 5.75	44.94	40.30	^a Sinemet 100/25 [MK]

■ LEVODOPA + CARBIDOPA**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.

Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

levodopa 200 mg + carbidopa 50 mg modified release tablet, 100

11663W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	96.96	40.30	^a Carbidopa and Levodopa Extended-release Tablets [DZ]

levodopa 200 mg + carbidopa 50 mg modified release tablet, 100

1255C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	67.34	40.30	^a Sinemet CR [MK]

■ LEVODOPA + CARBIDOPA

Note Special Pricing Arrangements apply.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

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.

Authority required (STREAMLINED)

5473

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

8970D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*11688.11	40.30	Duodopa [VE]

■ LEVODOPA + CARBIDOPA + ENTACAPONE**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.

Restricted benefit

Parkinson disease

Clinical criteria:

- Patient must be being treated with levodopa decarboxylase inhibitor combinations, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

Restricted benefit

Parkinson disease

Clinical criteria:

- Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100

9344T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*316.41	40.30	Stalevo 75/18.75/200mg [NV]

levodopa 100 mg + carbidopa 25 mg + entacapone 200 mg tablet, 100

8798C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*333.79	40.30	Stalevo 100/25/200mg [NV]

levodopa 200 mg + carbidopa 50 mg + entacapone 200 mg tablet, 100

9292C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*393.51	40.30	Stalevo 200/50/200mg [NV]

levodopa 50 mg + carbidopa 12.5 mg + entacapone 200 mg tablet, 100

8797B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*302.71	40.30	Stalevo 50/12.5/200mg [NV]

levodopa 150 mg + carbidopa 37.5 mg + entacapone 200 mg tablet, 100

8799D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*364.89	40.30	Stalevo 150/37.5/200mg [NV]

levodopa 125 mg + carbidopa 31.25 mg + entacapone 200 mg tablet, 100

9345W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*346.25	40.30	Stalevo 125/31.25/200mg [NV]

Adamantane derivatives**■ AMANTADINE****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.

Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must not be drug induced.

amantadine hydrochloride 100 mg capsule, 100

3016R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	38.60	39.85	Symmetrel 100 [NV]

Dopamine agonists**■ BROMOCRIPTINE**

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Restricted benefit

Acromegaly

Restricted benefit

Parkinson disease

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

- Patient must have had radiotherapy for this condition with incomplete resolution.

bromocriptine 2.5 mg tablet, 30

1443Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*33.23	34.48	Parlodel [SZ]

■ CABERGOLINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

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.

Restricted benefit

Parkinson disease

cabergoline 1 mg tablet, 30

8393R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.99	40.30	Cabaser [PF]

cabergoline 2 mg tablet, 30

8394T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	76.50	40.30	Cabaser [PF]

■ PRAMIPEXOLE

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

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.

Restricted benefit

Parkinson disease

pramipexole dihydrochloride monohydrate 125 microgram tablet, 30

9151P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.21	15.46	^a APO-Pramipexole [TX] ^a Sifrol [BY] ^a Simpral [AF]	^a Pramipexole AN [EA] ^a Simipex 0.125 [RW]

pramipexole dihydrochloride monohydrate 1 mg tablet, 100

9153R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	89.53	40.30	^a APO-Pramipexole [TX] ^a Sifrol [BY] ^a Simpral [AF]	^a Pramipexole AN [EA] ^a Simipex 1 [RW]

pramipexole dihydrochloride monohydrate 250 microgram tablet, 100

9152Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.36	30.61	^a APO-Pramipexole [TX] ^a Sifrol [BY] ^a Simpral [AF]	^a Pramipexole AN [EA] ^a Simipex 0.25 [RW]

■ PRAMIPEXOLE

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note No 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 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.

Restricted benefit

Parkinson disease

pramipexole dihydrochloride monohydrate 3.75 mg modified release tablet, 30

5145T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	93.37	40.30	^a APO-Pramipexole ER [TX] ^a Sifrol ER [BY]	^a Pramipexole XR GP [AF] ^a SIMIPEX XR [RW]

pramipexole dihydrochloride monohydrate 3 mg modified release tablet, 30

3421C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	78.11	40.30	^a APO-Pramipexole ER [TX] ^a Sifrol ER [BY]	^a Pramipexole XR GP [AF] ^a SIMIPEX XR [RW]

pramipexole dihydrochloride monohydrate 2.25 mg modified release tablet, 30

5143Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	57.28	40.30	^a APO-Pramipexole ER [TX] ^a Sifrol ER [BY]	^a Pramipexole XR GP [AF] ^a SIMIPEX XR [RW]

pramipexole dihydrochloride monohydrate 375 microgram modified release tablet, 30

3418X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.24	20.49	^a APO-Pramipexole ER [TX] ^a Sifrol ER [BY]	^a Pramipexole XR GP [AF] ^a SIMIPEX XR [RW]

pramipexole dihydrochloride monohydrate 1.5 mg modified release tablet, 30

3420B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	42.02	40.30	^a APO-Pramipexole ER [TX] ^a Sifrol ER [BY]	^a Pramipexole XR GP [AF] ^a SIMIPEX XR [RW]

pramipexole dihydrochloride monohydrate 4.5 mg modified release tablet, 30

3422D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	111.42	40.30	^a APO-Pramipexole ER [TX] ^a Sifrol ER [BY]	^a Pramipexole XR GP [AF] ^a SIMIPEX XR [RW]

pramipexole dihydrochloride monohydrate 750 microgram modified release tablet, 30

3419Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	26.75	28.00	^a APO-Pramipexole ER [TX] ^a Sifrol ER [BY]	^a Pramipexole XR GP [AF] ^a SIMIPEX XR [RW]

■ PRAMIPEXOLE

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note This drug is not PBS-subsidised for Restless Legs Syndrome secondary to other causes

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Primary severe restless legs syndrome

Clinical criteria:

- Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome, **AND**
- Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

- (a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and
- (b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and
- (c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and
- (d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

pramipexole dihydrochloride monohydrate 125 microgram tablet, 30

9393J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	14.21	15.46	Sifrol [BY]

pramipexole dihydrochloride monohydrate 250 microgram tablet, 100

9394K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	29.36	30.61	Sifrol [BY]

■ ROTIGOTINE**Restricted benefit**

Parkinson disease

Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

rotigotine 4 mg/24 hours patch, 28

2384L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	93.04	40.30	Neupro [UC]

rotigotine 8 mg/24 hours patch, 28

11140H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	114.40	40.30	Neupro [UC]

rotigotine 6 mg/24 hours patch, 28

2410W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	104.03	40.30	Neupro [UC]

■ ROTIGOTINE**Restricted benefit**

Parkinson disease

Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

rotigotine 2 mg/24 hours patch, 28

2385M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	72.66	40.30	Neupro [UC]

*Monoamine oxidase B inhibitors***■ RASAGILINE****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Restricted benefit**

Parkinson disease

rasagiline 1 mg tablet, 30

1952R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	86.08	40.30	^a Azilect [TB]	^a Pharmacor Rasagiline [CR]
						^a Rasagiline-Teva [EV]	

■ SAFINAMIDE**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Restricted benefit**

Parkinson disease

Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

safinamide 50 mg tablet, 30

11656L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	63.83	40.30	Xadago [CS]

safinamide 100 mg tablet, 30

11666B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	116.18	40.30	Xadago [CS]

■ SELEGILINE**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.

Restricted benefit

Late stage Parkinson disease

Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

selegiline hydrochloride 5 mg tablet, 100

1973W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	53.52	40.30	Eldepryl [AS]

*Other dopaminergic agents***■ ENTACAPONE****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.

Restricted benefit

Parkinson disease

Clinical criteria:

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

entacapone 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8367J NP	2	4	..	*221.57	40.30	Comtan [NV]

■ **PSYCHOLEPTICS****ANTIPSYCHOTICS***Phenothiazines with aliphatic side-chain*■ **CHLORPROMAZINE****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.

chlorpromazine hydrochloride 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1199D NP	1	5	..	19.25	20.50	Largactil [SW]

chlorpromazine hydrochloride 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1196Y NP	1	5	..	14.62	15.87	Largactil [SW]

chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1195X NP	1	..	..	21.40	22.65	Largactil [SW]

chlorpromazine hydrochloride 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1197B NP	1	5	..	15.06	16.31	Largactil [SW]

chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1201F NP	‡1	5	..	15.97	17.22	Largactil [SW]

Phenothiazines with piperidine structure■ **PERICIAZINE****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.

periciazine 2.5 mg tablet, 84

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11413Q NP	1	5	..	14.45	15.70	Neulactil [SW]

periciazine 10 mg tablet, 84

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11427K NP	1	5	..	17.58	18.83	Neulactil [SW]

periciazine 2.5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3052P NP	1	5	..	14.49	15.74	Neulactil [SW]

periciazine 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3053Q NP	1	5	..	17.68	18.93	Neulactil [SW]

Butyrophenone derivatives■ **HALOPERIDOL****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.

haloperidol 500 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2761H NP	1	5	..	14.77	16.02	Serenace [QA]

haloperidol 1.5 mg tablet, 100

2767P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.15	16.40	Serenace [QA]

haloperidol 5 mg/mL injection, 10 x 1 mL ampoules

2768Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	22.68	23.93	Serenace [QA]

haloperidol 2 mg/mL oral liquid, 100 mL

2763K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	22.00	23.25	Serenace [QA]

haloperidol 5 mg tablet, 50

2770T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.00	16.25	Serenace [QA]

■ HALOPERIDOL DECANOATE**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.

haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL ampoules

2765M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	27.93	29.18	Haldol decanoate [JC]

haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules

2766N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	44.47	40.30	Haldol decanoate [JC]

*Indole derivatives***■ LURASIDONE****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.

Authority required (STREAMLINED)**4246**

Schizophrenia

lurasidone hydrochloride 40 mg tablet, 30

10526B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	78.11	40.30	Latuda [SE]

lurasidone hydrochloride 80 mg tablet, 30

10529E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	144.74	40.30	Latuda [SE]

■ ZIPRASIDONE**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.

Authority required (STREAMLINED)**4246**

Schizophrenia

Authority required (STREAMLINED)**5742**

Acute mania or mixed episodes

Clinical criteria:

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

ziprasidone 60 mg capsule, 60

9072L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	145.02	40.30	^a APO-Ziprasidone [TX] ^a Ziprasidone GH [GQ]	^a Zeldox [PF] ^a ZIPROX [RW]

ziprasidone 80 mg capsule, 60

9073M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	189.77	40.30	^a APO-Ziprasidone [TX] ^a Ziprasidone GH [GQ]	^a Zeldox [PF] ^a ZIPROX [RW]

ziprasidone 40 mg capsule, 60

9071K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	100.83	40.30	^a APO-Ziprasidone [TX] ^a Ziprasidone GH [GQ]	^a Zeldox [PF] ^a ZIPROX [RW]

ziprasidone 20 mg capsule, 60

9070J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	56.08	40.30	^a APO-Ziprasidone [TX] ^a Ziprasidone GH [GQ]	^a Zeldox [PF] ^a ZIPROX [RW]

*Thioxanthene derivatives***FLUPENTIXOL DECANOATE****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.

flupentixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules

2255Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.73	24.98	Fluanxol Depot [LU]

flupentixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules

2257T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	48.83	40.30	Fluanxol Concentrated Depot [LU]

ZUCLOPENTHIXOL DECANOATE**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.

zuclopentixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules

8097E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	29.58	30.83	Clopixol Depot [LU]

*Diazepines, oxazepines, thiazepines and oxepines***ASENAPINE****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.

Authority required (STREAMLINED)**4246**

Schizophrenia

Authority required (STREAMLINED)**5773**

Acute mania or mixed episodes

Clinical criteria:

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be limited to up to 6 months per episode.

Authority required (STREAMLINED)**5719**

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy, **AND**
- The treatment must be as monotherapy.

asenapine 5 mg sublingual wafer, 60

5140M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	141.58	40.30	Saphris [LU]

asenapine 10 mg sublingual wafer, 60

5141N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	229.65	40.30	Saphris [LU]

■ OLANZAPINE**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.

Authority required (STREAMLINED)**5856**

Schizophrenia

Authority required (STREAMLINED)**5869**

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

olanzapine 2.5 mg tablet, 28

8170B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.25	15.50	^a APO-Olanzapine [TX] ^a Olanzapine APOTEX [GX] ^a Olanzapine RBX [RA] ^a Ozin 2.5 [DO] ^a Zypine [AF]	^a Olanzapine AN [EA] ^a Olanzapine-DRLA [RZ] ^a Olanzapine Sandoz [SZ] ^a PRYZEX [RW]
			^b 3.00	17.25	15.50	^a Zyprexa [LY]	

olanzapine 10 mg tablet, 28

8187X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.55	23.80	^a APO-Olanzapine [TX] ^a Olanzapine APOTEX [GX] ^a Olanzapine RBX [RA] ^a Ozin 10 [DO] ^a Zypine [AF]	^a Olanzapine AN [EA] ^a Olanzapine-DRLA [RZ] ^a Olanzapine Sandoz [SZ] ^a PRYZEX [RW]
			^b 3.00	25.55	23.80	^a Zyprexa [LY]	

olanzapine 5 mg tablet, 28

8185T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.96	18.21	^a APO-Olanzapine [TX] ^a Olanzapine APOTEX [GX] ^a Olanzapine RBX [RA] ^a Ozin 5 [DO] ^a Zypine [AF]	^a Olanzapine AN [EA] ^a Olanzapine-DRLA [RZ] ^a Olanzapine Sandoz [SZ] ^a PRYZEX [RW]
			^b 3.00	19.96	18.21	^a Zyprexa [LY]	

■ OLANZAPINE

Note Pharmaceutical benefits that have the form olanzapine tablet 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution.

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.

Authority required (STREAMLINED)**5856**

Schizophrenia

Authority required (STREAMLINED)**5869**

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

olanzapine 7.5 mg tablet, 28

1041T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.79	21.04	^a Olanzapine generichealth 7.5 [GQ]

olanzapine 7.5 mg tablet, 28

8186W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.79	21.04	^a APO-Olanzapine [TX] ^a Olanzapine APOTEX [GX]	^a Olanzapine AN [EA] ^a Olanzapine-DRLA [RZ]

^a Olanzapine RBX [RA]	^a Olanzapine Sandoz [SZ]
^a Ozin 7.5 [DO]	^a PRYZEX [RW]
^a Zypine [AF]	
^a Zyprexa [LY]	

^B3.00 22.79 21.04

■ OLANZAPINE

Note Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

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.

Authority required (STREAMLINED)

5856

Schizophrenia

Authority required (STREAMLINED)

5869

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

olanzapine 5 mg orally disintegrating tablet, 28

3381Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.96	18.21	^a APO-Olanzapine ODT [TX] ^a Olanzapine ODT-DRLA [RZ] ^a Olanzapine Sandoz ODT 5 [SZ]	^a Olanzapine AN ODT [EA] ^a Olanzapine ODT generichealth 5 [GQ] ^a PRYZEX ODT [RW]

olanzapine 5 mg wafer, 28

8433W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.96	18.21	^a Zypine ODT [AF]
			^B 3.00	19.96	18.21	^a Zyprexa Zydis [LY]

■ OLANZAPINE

Note Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.

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.

Authority required (STREAMLINED)

5856

Schizophrenia

Authority required (STREAMLINED)

5869

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

olanzapine 10 mg orally disintegrating tablet, 28

3382B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.55	23.80	^a APO-Olanzapine ODT [TX] ^a Olanzapine ODT-DRLA [RZ] ^a Olanzapine Sandoz ODT 10 [SZ]	^a Olanzapine AN ODT [EA] ^a Olanzapine ODT generichealth 10 [GQ] ^a PRYZEX ODT [RW]

olanzapine 10 mg wafer, 28

8434X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	22.55	23.80	^a Zypine ODT [AF]
			^B 3.00	25.55	23.80	^a Zyprexa Zydis [LY]

■ OLANZAPINE

Note Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

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.

Authority required (STREAMLINED)

5856

Schizophrenia

Authority required (STREAMLINED)**5869**

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

olanzapine 15 mg orally disintegrating tablet, 28

3384D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.09	29.34	^a APO-Olanzapine ODT [TX] ^a Olanzapine Sandoz ODT 15 [SZ]	^a Olanzapine AN ODT [EA] ^a PRYZEX ODT [RW]

olanzapine 15 mg wafer, 28

8952E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	28.09	29.34	^a Zypine ODT [AF]
			^B 3.00	31.09	29.34	^a Zyprexa Zydis [LY]

■ OLANZAPINE

Note Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

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.

Authority required (STREAMLINED)**5856**

Schizophrenia

Authority required (STREAMLINED)**5869**

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

olanzapine 20 mg wafer, 28

8953F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	33.63	34.88	^a Zypine ODT [AF]
			^B 3.00	36.63	34.88	^a Zyprexa Zydis [LY]

olanzapine 20 mg orally disintegrating tablet, 28

3385E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.63	34.88	^a APO-Olanzapine ODT [TX] ^a Olanzapine Sandoz ODT 20 [SZ]	^a Olanzapine AN ODT [EA] ^a PRYZEX ODT [RW]

■ OLANZAPINE

Caution Monitor for post-injection syndrome for at least two hours after each injection.

Note Special Pricing Arrangements apply.

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.

Authority required (STREAMLINED)**4304**

Schizophrenia

olanzapine 405 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack

9303P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	496.16	40.30	Zyprexa Relprevv [LY]

olanzapine 210 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack

9294E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*496.17	40.30	Zyprexa Relprevv [LY]

olanzapine 300 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack

9295F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*804.15	40.30	Zyprexa Relprevv [LY]

■ QUETIAPINE

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.

Authority required (STREAMLINED)**4246**

Schizophrenia

Authority required (STREAMLINED)**5611**

Acute mania

Clinical criteria:

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

Authority required (STREAMLINED)**5639**

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

quetiapine 300 mg tablet, 60

8580N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.51	40.30	^a APO-Quetiapine [TX] ^a Kaptan [ER] ^a Quetia 300 [RW] ^a Quetiapine AN [EA] ^a Quetiapine GH 300 [GQ] ^a Quetiapine Sandoz [SZ] ^a Syquet [AF]	^a Chem mart Quetiapine [CH] ^a Pharmacor Quetiapine 300 [CR] ^a Quetiapine Actavis 300 [ED] ^a Quetiapine-DRLA [RZ] ^a Quetiapine RBX [RA] ^a Seroquel [AP] ^a Terry White Chemists Quetiapine [TW]

quetiapine 200 mg tablet, 60

8458E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.98	35.23	^a APO-Quetiapine [TX] ^a Kaptan [ER] ^a Quetia 200 [RW] ^a Quetiapine AN [EA] ^a Quetiapine GH 200 [GQ] ^a Quetiapine Sandoz [SZ] ^a Syquet [AF]	^a Chem mart Quetiapine [CH] ^a Pharmacor Quetiapine 200 [CR] ^a Quetiapine Actavis 200 [ED] ^a Quetiapine-DRLA [RZ] ^a Quetiapine RBX [RA] ^a Seroquel [AP] ^a Terry White Chemists Quetiapine [TW]

quetiapine 50 mg modified release tablet, 60

9202H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.16	24.41	^a APO-Quetiapine XR [TX] ^a QUETIAPINE-AS XR [RW] ^b 5.16	^a QUEPINE XR [RF] ^a Tevatiapine XR [SZ]
				28.32	24.41	^a Seroquel XR [AP]	

quetiapine 100 mg tablet, 90

8457D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.00	29.25	^a APO-Quetiapine [TX] ^a Kaptan [ER] ^a Quetia 100 [RW] ^a Quetiapine AN [EA] ^a Quetiapine GH 100 [GQ] ^a Quetiapine Sandoz [SZ] ^a Syquet [AF]	^a Chem mart Quetiapine [CH] ^a Pharmacor Quetiapine 100 [CR] ^a Quetiapine Actavis 100 [ED] ^a Quetiapine-DRLA [RZ] ^a Quetiapine RBX [RA] ^a Seroquel [AP] ^a Terry White Chemists Quetiapine [TW]

quetiapine 200 mg modified release tablet, 60

9203J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	45.46	40.30	^a APO-Quetiapine XR [TX] ^a QUETIAPINE-AS XR [RW] ^b 2.15	^a QUEPINE XR [RF] ^a Tevatiapine XR [SZ]
				47.61	40.30	^a Seroquel XR [AP]	

quetiapine 300 mg modified release tablet, 60

9204K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	55.12	40.30	^a APO-Quetiapine XR [TX]	^a QUEPINE XR [RF]
						^a QUETIAPINE-AS XR [RW]	^a Tevatiapine XR [SZ]
			^B 2.15	57.27	40.30	^a Seroquel XR [AP]	

quetiapine 400 mg modified release tablet, 60

9205L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	70.97	40.30	^a APO-Quetiapine XR [TX]	^a QUEPINE XR [RF]
						^a QUETIAPINE-AS XR [RW]	^a Tevatiapine XR [SZ]
			^B 2.15	73.12	40.30	^a Seroquel XR [AP]	

quetiapine 150 mg modified release tablet, 60

5458G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.00	29.25	^a QUEPINE XR [RW]	^a Tevatiapine XR [SZ]
			^B 10.75	38.75	29.25	^a Seroquel XR [AP]	

■ QUETIAPINE

Note No increase in the maximum quantity or number of units may be authorised.

Note Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)**7916**

Schizophrenia

Authority required (STREAMLINED)**7927**

Acute mania

Clinical criteria:

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy.

Authority required (STREAMLINED)**7893**

Bipolar I disorder

Clinical criteria:

- The treatment must be maintenance therapy.

quetiapine 25 mg tablet, 60

8456C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.32	18.57	^a APO-Quetiapine [TX]	^a Chem mart Quetiapine [CH]
						^a Kaptan [ER]	^a Pharmacor Quetiapine 25 [CR]
						^a Quetia 25 [RW]	^a Quetiapine AN [EA]
						^a Quetiapine-DRLA [RZ]	^a Quetiapine GH 25 [GQ]
						^a Quetiapine RBX [RA]	^a Quetiapine Sandoz [SZ]
						^a Seroquel [AP]	^a Syquet [AF]
						^a Terry White Chemists Quetiapine [TW]	

Benzamides**■ AMISULPRIDE**

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.

Authority required (STREAMLINED)**4246**

Schizophrenia

amisulpride 100 mg tablet, 30

8594H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.44	19.69	^a Amisulpride 100 Winthrop [WA]	^a Amisulpride AN [EA]
						^a Amisulpride Sandoz [SZ]	^a Amisulpride Sandoz Pharma [HX]
						^a APO-Amisulpride [TX]	^a Pharmacor Amisulpride [CR]
						^a Solian 100 [SW]	^a Sulprix [AF]

amisulpride 200 mg tablet, 60

8595J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.47	40.30	^a Amisulpride 200 Winthrop [WA] ^a Amisulpride Sandoz [SZ] ^a Pharmacor Amisulpride [CR] ^a Sulprix [AF]	^a Amisulpride AN [EA] ^a APO-Amisulpride [TX] ^a Solian 200 [SW]

amisulpride 400 mg tablet, 60

8596K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	65.85	40.30	^a Amipride 400 [RW] ^a Amisulpride AN [EA] ^a Amisulpride Sandoz Pharma [HX] ^a Pharmacor Amisulpride [CR] ^a Sulprix [AF]	^a Amisulpride 400 Winthrop [WA] ^a Amisulpride Sandoz [SZ] ^a APO-Amisulpride [TX] ^a Solian 400 [SW]

amisulpride 100 mg/mL oral liquid, 60 mL

8736T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*140.87	40.30	Solian Solution [SW]

Other antipsychotics**■ ARIPIPRAZOLE****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.

Authority required (STREAMLINED)**4246**

Schizophrenia

aripiprazole 30 mg tablet, 30

8720Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	180.03	40.30	^a Abilify [OS] ^a APO-Aripiprazole [TX] ^a Aripiprazole GH [GQ] ^a Tevaripiprazole [TB]	^a Abyraz [AF] ^a Aripiprazole AN [EA] ^a Aripiprazole Sandoz [SZ]

aripiprazole 300 mg modified release injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

10224D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	300.30	40.30	Abilify Maintena [LU]

aripiprazole 400 mg modified release injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

10219W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	374.09	40.30	Abilify Maintena [LU]

aripiprazole 15 mg tablet, 30

8718W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	125.11	40.30	^a Abilify [OS] ^a APO-Aripiprazole [TX] ^a Aripiprazole GH [GQ] ^a Tevaripiprazole [TB]	^a Abyraz [AF] ^a Aripiprazole AN [EA] ^a Aripiprazole Sandoz [SZ]

aripiprazole 10 mg tablet, 30

8717T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	91.55	40.30	^a Abilify [OS] ^a APO-Aripiprazole [TX] ^a Aripiprazole GH [GQ] ^a Tevaripiprazole [TB]	^a Abyraz [AF] ^a Aripiprazole AN [EA] ^a Aripiprazole Sandoz [SZ]

aripiprazole 20 mg tablet, 30

8719X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	149.79	40.30	^a Abilify [OS] ^a APO-Aripiprazole [TX] ^a Aripiprazole GH [GQ] ^a Tevaripiprazole [TB]	^a Abyraz [AF] ^a Aripiprazole AN [EA] ^a Aripiprazole Sandoz [SZ]

■ BREXPIPIRAZOLE**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.

Authority required (STREAMLINED)

4246

Schizophrenia

brexpiprazole 2 mg tablet, 30

11188W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	142.76	40.30	Rexulti [LU]

brexpiprazole 4 mg tablet, 30

11184P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	142.76	40.30	Rexulti [LU]

brexpiprazole 1 mg tablet, 30

11189X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	142.76	40.30	Rexulti [LU]

brexpiprazole 3 mg tablet, 30

11190Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	142.76	40.30	Rexulti [LU]

■ **PALIPERIDONE**

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.

Authority required (STREAMLINED)

4246

Schizophrenia

paliperidone 100 mg modified release injection, 1 syringe

5107T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	373.55	40.30	Invega Sustenna [JC]

paliperidone 50 mg modified release injection, 1 syringe

5102M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	235.59	40.30	Invega Sustenna [JC]

paliperidone 75 mg modified release injection, 1 syringe

5103N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	304.93	40.30	Invega Sustenna [JC]

paliperidone 6 mg modified release tablet, 28

9141D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	126.40	40.30	Invega [JC]

paliperidone 150 mg modified release injection, 1 syringe

5109X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	373.55	40.30	Invega Sustenna [JC]

paliperidone 25 mg modified release injection, 1 syringe

5100K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	122.80	40.30	Invega Sustenna [JC]

paliperidone 3 mg modified release tablet, 28

9140C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	68.36	40.30	Invega [JC]

paliperidone 9 mg modified release tablet, 28

9142E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	183.85	40.30	Invega [JC]

■ **PALIPERIDONE**

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.

Note Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required (STREAMLINED)

6832

Schizophrenia

Clinical criteria:

- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months.

paliperidone 525 mg/2.625 mL modified release injection, 2.625 mL syringe

11066K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	1105.39	40.30	Invega Trinza [JC]

paliperidone 175 mg/0.875 mL modified release injection, 0.875 mL syringe

11085K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	696.43	40.30	Invega Trinza [JC]

paliperidone 263 mg/1.315 mL modified release injection, 1.315 mL syringe

11072R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	904.42	40.30	Invega Trinza [JC]

paliperidone 350 mg/1.75 mL modified release injection, 1.75 mL syringe

11094X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	1105.39	40.30	Invega Trinza [JC]

▪ **RISPERIDONE**

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.

Authority required (STREAMLINED)

4246

Schizophrenia

Authority required (STREAMLINED)

5907

Acute mania

Clinical criteria:

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as adjunctive therapy to mood stabilisers, **AND**
- The treatment must be limited to up to 6 months per episode.

risperidone 1 mg tablet, 60

3169T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.72	18.97	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Rispericor 1 [CR] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone AMNEAL [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]

risperidone 4 mg tablet, 60

3172Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.18	40.30	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Risperidone AMNEAL [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]

risperidone 3 mg tablet, 60

3171X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.48	34.73	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Risperidone AMNEAL [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]

risperidone 2 mg tablet, 60

3170W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.75	27.00	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Rispericor 2 [CR] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone AMNEAL [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]

risperidone 1 mg/mL oral liquid, 100 mL

8100H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	112.94	40.30	Risperdal [JC]

■ RISPERIDONE**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.

Authority required (STREAMLINED)**6897**

Severe behavioural disturbances

Clinical criteria:

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

Population criteria:

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)**6938**

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

Population criteria:

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

risperidone 2 mg tablet, 60

9079W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	25.75	27.00	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Rispericor 2 [CR] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone AMNEAL [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]

■ RISPERIDONE**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.

Authority required (STREAMLINED)**4246**

Schizophrenia

Authority required (STREAMLINED)**5912**

Bipolar I disorder

Clinical criteria:

- The condition must be refractory to treatment, **AND**
- The treatment must be in combination with lithium or sodium valproate, **AND**
- The treatment must be maintenance therapy.

risperidone 50 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

8782F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	2	5	..	*423.89	40.30	Risperdal Consta [JC]

risperidone 25 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

8780D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	2	5	..	*266.71	40.30	Risperdal Consta [JC]

risperidone 37.5 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

8781E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	2	5	..	*345.71	40.30	Risperdal Consta [JC]

■ RISPERIDONE
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.

Note For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)
5903

Schizophrenia

risperidone 500 microgram tablet, 20

1846E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
(NP)	3	5	..	*18.61	19.86	^a APO-Risperidone [TX]	^a Risperdal [JC]

risperidone 500 microgram tablet, 60

8869T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
(NP)	1	5	..	18.61	19.86	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Risperidone AMNEAL [EF] ^a Rispernia [ER]	^a Ozidal [RA] ^a Rispericor 0.5 [CR] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]

■ RISPERIDONE

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

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.

Authority required (STREAMLINED)
5993

Behavioural disturbances

Clinical criteria:

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Authority required (STREAMLINED)
6897

Severe behavioural disturbances

Clinical criteria:

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

Population criteria:

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)

6938

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

Population criteria:

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

risperidone 1 mg tablet, 60

8789N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	17.72	18.97	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Rispericor 1 [CR] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone AMNEAL [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]

risperidone 1 mg/mL oral liquid, 100 mL

9293D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	112.94	40.30	Risperdal [JC]

■ RISPERIDONE

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

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.

Note For items 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**6010**

Behavioural disturbances

Clinical criteria:

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Authority required (STREAMLINED)**6898**

Severe behavioural disturbances

Clinical criteria:

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

Population criteria:

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)**6899**

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

Population criteria:

- Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

risperidone 500 microgram tablet, 20

1842Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	2	..	*18.61	19.86	^a APO-Risperidone [TX]	^a Risperdal [JC]

risperidone 500 microgram tablet, 60

8787L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	18.61	19.86	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Risperidone AMNEAL [EF] ^a Rispernia [ER]	^a Ozidal [RA] ^a Rispericor 0.5 [CR] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]

ANXIOLYTICS*Benzodiazepine derivatives***■ ALPRAZOLAM**

Note The panic disorder must not be attributable to some known organic factor.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Panic disorder

Clinical criteria:

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

alprazolam 1 mg tablet, 10

11186R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	18.29	19.54	^a Alprax 1 [QA]	^a Kalma 1 [AF]

alprazolam 500 microgram tablet, 10

11187T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.23	18.48	^a Alprax 0.5 [QA]	^a Kalma 0.5 [AF]

alprazolam 250 microgram tablet, 10

11205R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.22	17.47	Kalma 0.25 [AF]	

■ DIAZEPAM**diazepam 5 mg tablet, 50**

5072Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.87	14.12	^a Antenex 5 [AF] ^a Valpam 5 [RW]	^a APO-Diazepam [TX]
			^B 3.30	16.17	14.12	^a Valium [RO]	

diazepam 2 mg tablet, 50

5071X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.80	14.05	^a APO-Diazepam [TX]	^a Valpam 2 [RW]
			^B 2.99	15.79	14.05	^a Antenex 2 [AF]	

diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules

5073B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	17.50	18.75	Hospira Pty Limited [PF]	

■ DIAZEPAM**Authority required**

Chronic spasticity

Population criteria:

- Patient must be under 18 years of age.

diazepam 1 mg/mL oral liquid, 100 mL

2669L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	..	..	43.34	40.30	Diazepam Elixir [ON]	

■ DIAZEPAM

Note Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for

- (i) the treatment of disabling spasticity; or
- (ii) malignant neoplasia (late stage); or
- (iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or
- (iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

diazepam 5 mg tablet, 50

3162K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.87	14.12	^a Antenex 5 [AF]	^a APO-Diazepam [TX]
			..	12.87	14.12	^a Valpam 5 [RW]	
			^B 3.30	16.17	14.12	^a Valium [RO]	

diazepam 2 mg tablet, 50

3161J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.80	14.05	^a APO-Diazepam [TX]	^a Valpam 2 [RW]
			..	12.80	14.05	^a Antenex 2 [AF]	
			^B 2.99	15.79	14.05		

■ DIAZEPAM

Note Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for

- (i) the treatment of disabling spasticity; or
- (ii) malignant neoplasia (late stage); or
- (iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or
- (iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Note Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules

2558P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	17.50	18.75	Hospira Pty Limited [PF]
			..	17.50	18.75	

■ OXAZEPAM

oxazepam 15 mg tablet, 25

5192G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	12.90	14.15	^a Alepam 15 [AF]
			..	12.90	14.15	^a Serepax [QA]
			^B 2.66	15.56	14.15	

oxazepam 30 mg tablet, 25

5193H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.56	13.81	^a Alepam 30 [AF]	^a APO-Oxazepam [TX]
			..	12.56	13.81	^a Murelax [RW]	
			^B 2.33	14.89	13.81	^a Serepax [QA]	

■ OXAZEPAM

Note Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of oxazepam below.

oxazepam 15 mg tablet, 25

3132W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	12.90	14.15	^a Alepam 15 [AF]
			..	12.90	14.15	^a Serepax [QA]
			^B 2.66	15.56	14.15	

oxazepam 30 mg tablet, 25

3133X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.56	13.81	^a Alepam 30 [AF]	^a APO-Oxazepam [TX]
			..	12.56	13.81	^a Murelax [RW]	
			^B 2.33	14.89	13.81	^a Serepax [QA]	

■ OXAZEPAM

Authority required

Malignant neoplasia (late stage)

Authority required

Anxiety

Clinical criteria:

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

Authority required

Anxiety

Clinical criteria:

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

oxazepam 15 mg tablet, 25

3134Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*14.33	15.58	^a Alepam 15 [AF]
			^B 5.32	*19.65	15.58	^a Serepax [QA]

oxazepam 30 mg tablet, 25

3135B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*13.65	14.90	^a Alepam 30 [AF]	^a APO-Oxazepam [TX]
						^a Murelax [RW]	
			^B 4.66	*18.31	14.90	^a Serepax [QA]	

HYPNOTICS AND SEDATIVES*Benzodiazepine derivatives***■ NITRAZEPAM****nitrazepam 5 mg tablet, 25**

5189D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	13.09	14.34	^a Alodorm [AF]
			^B 1.24	14.33	14.34	^a Mogadon [IL]

■ NITRAZEPAM

Note Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam below.

nitrazepam 5 mg tablet, 25

2723H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	13.09	14.34	^a Alodorm [AF]
			^B 1.24	14.33	14.34	^a Mogadon [IL]

■ NITRAZEPAM**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.

Authority required

Myoclonic epilepsy

Authority required

Malignant neoplasia (late stage)

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**

- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

nitrazepam 5 mg tablet, 25

2732T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*14.71	15.96	^a Alodorm [AF]
			^B 2.48	*17.19	15.96	^a Mogadon [IL]

■ TEMAZEPAM**temazepam 10 mg tablet, 25**

5221T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.56	13.81	^a APO-Temazepam [TX]	^a Temaze [AF]
			^B 3.48	16.04	13.81	^a Temtabs [FM] ^a Normison [QA]	

■ TEMAZEPAM

Note Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam.

temazepam 10 mg tablet, 25

2089Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.56	13.81	^a APO-Temazepam [TX]	^a Temaze [AF]
			^B 3.48	16.04	13.81	^a Temtabs [FM] ^a Normison [QA]	

■ TEMAZEPAM**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.

Authority required

Malignant neoplasia (late stage)

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

temazepam 10 mg tablet, 25

2088X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*13.65	14.90	^a APO-Temazepam [TX]	^a Temaze [AF]
			^B 6.96	*20.61	14.90	^a Temtabs [FM] ^a Normison [QA]	

■ PSYCHOANALEPTICS**ANTIDEPRESSANTS**

Non-selective monoamine reuptake inhibitors

■ AMITRIPTYLINE**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.

amitriptyline hydrochloride 10 mg tablet, 50

2417F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	13.99	15.24	^a Amitriptyline Alphapharm 10	^a APO-Amitriptyline 10 [TX]
						[AL]	

^a Chem mart Amitriptyline [CH] ^a ENTRIP [RW]
^a Terry White Chemists
 Amitriptyline [TW]
^a Endep 10 [AF]

amitriptyline hydrochloride 50 mg tablet, 50

2429W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	14.58	15.83	^a Amitriptyline Alphapharm 50 [AL] ^a Chem mart Amitriptyline [CH] ^a Terry White Chemists Amitriptyline [TW]	^a APO-Amitriptyline 50 [TX] ^a ENTRIP [RW]
			^B 1.95	16.53	15.83	^a Endep 50 [AF]	

amitriptyline hydrochloride 25 mg tablet, 50

2418G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	14.18	15.43	^a Amitriptyline Alphapharm 25 [AL] ^a Chem mart Amitriptyline [CH] ^a Terry White Chemists Amitriptyline [TW]	^a APO-Amitriptyline 25 [TX] ^a ENTRIP [RW]
			^B 1.96	16.14	15.43	^a Endep 25 [AF]	

■ CLOMIPRAMINE**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.

Restricted benefit

Cataplexy

Clinical criteria:

- The condition must be associated with narcolepsy.

Restricted benefit

Obsessive-compulsive disorder

Restricted benefit

Phobic disorders

Population criteria:

- Patient must be an adult.

clomipramine hydrochloride 25 mg tablet, 50

1561E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	17.42	18.67	^a APO-Clomipramine [TX] ^a Placil [AF]	^a GenRx Clomipramine [GX]
			^B 4.41	21.83	18.67	^a Anafranil 25 [SZ]	

■ DOSULEPIN (DOTHIEPIN)**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.

dosulepin (dothiepin) hydrochloride 25 mg capsule, 50

1357K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	14.05	15.30	^a Dosulepin Mylan [AL]	^a Dothep 25 [AF]

dosulepin (dothiepin) hydrochloride 75 mg tablet, 30

1358L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	14.05	15.30	^a Dosulepin Mylan [AL]	^a Dothep 75 [AF]

■ DOXEPIIN**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.

doxepin 25 mg capsule, 50

1013H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	15.63	16.88	Deptran 25 [AF]
			^B 7.51	23.14	16.88	Sinequan [PF]

doxepin 50 mg tablet, 50

1012G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	14.73	15.98	Deptran 50 [AF]

doxepin 10 mg capsule, 50

1011F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	14.68	15.93	Deptran 10 [AF]
			^B 7.51	22.19	15.93	Sinequan [PF]

■ IMIPRAMINE**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.

imipramine hydrochloride 25 mg tablet, 50

2421K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.12	20.37	Tofranil 25 [GH]

imipramine hydrochloride 10 mg tablet, 50

2420J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	15.75	17.00	Tofranil 10 [GH]

■ NORTRIPTYLINE**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.

Restricted benefit

Major depression

Clinical criteria:

- The treatment must be for use when other anti-depressant therapy has failed.

Restricted benefit

Major depression

Clinical criteria:

- The treatment must be for use when other anti-depressant therapy is contraindicated.

nortriptyline 10 mg tablet, 50

2522R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	16.26	17.51	^a Allegron [RW]	^a NortriTABS 10 mg [GH]

nortriptyline 25 mg tablet, 50

2523T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	17.50	18.75	^a Allegron [RW]	^a NortriTABS 25 mg [GH]

Selective serotonin reuptake inhibitors**■ CITALOPRAM****Restricted benefit**

Major depressive disorders

citalopram 10 mg tablet, 28

8702B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.45	13.70	^a Celapram [AF] ^a Citalopram AN [EF]	^a Citalopram Actavis [EA] ^a Talam [RW]

citalopram 40 mg tablet, 28

8703C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.67	14.92	^a APO-Citalopram [TX] ^a Citalopram Actavis [ED] ^a Citalopram Sandoz [SZ]	^a Celapram [AF] ^a Citalopram AN [EA] ^a Talam [RW]

citalopram 20 mg tablet, 28

8220P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.78	14.03	^a APO-Citalopram [TX] ^a Chem mart Citalopram [CH] ^a Citalopram AN [EA] ^a Talam [RW]	^a Celapram [AF] ^a Citalopram Actavis [ED] ^a Citalopram Sandoz [SZ] ^a Terry White Chemists Citalopram [TW]
			^B 10.69	23.47	14.03	^a Cipramil [LU]	

■ **ESCITALOPRAM****Restricted benefit**

Major depressive disorders

escitalopram 20 mg tablet, 28

8701Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.60	14.85	^a APO-Escitalopram [TX]	^a Blooms the Chemist Escitalopram [IB]
						^a Chem mart Escitalopram [CH]	^a Cilopam-S [ER]
						^a Escitalopram AN [EA]	^a Escitalopram-DRLA [RZ]
						^a Escitalopram GH [HQ]	^a Escitalopram Sandoz [HX]
						^a Esipram [CF]	^a Esitalo [SZ]
						^a Lexam 20 [RW]	^a LoxaLate [AF]
						^a Pharmacor Escitalopram 20 [CR]	^a Terry White Chemists Escitalopram [TW]
			^B 12.06	25.66	14.85	^a Lexapro [LU]	

escitalopram 10 mg tablet, 28

8700X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.58	14.83	^a APO-Escitalopram [TX]	^a Blooms the Chemist Escitalopram [IB]
						^a Chem mart Escitalopram [CH]	^a Cilopam-S [ER]
						^a Escitalopram AN [EA]	^a Escitalopram-DRLA [RZ]
						^a Escitalopram GH [HQ]	^a Escitalopram Sandoz [HX]
						^a Esipram [CF]	^a Esitalo [SZ]
						^a Lexam 10 [RW]	^a LoxaLate [AF]
						^a Pharmacor Escitalopram 10 [CR]	^a Terry White Chemists Escitalopram [TW]
			^B 11.72	25.30	14.83	^a Lexapro [LU]	

■ **ESCITALOPRAM****Restricted benefit**

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

escitalopram 20 mg tablet, 28

9433L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	13.60	14.85	^a Esipram [CF]
			^B 12.06	25.66	14.85	^a Lexapro [LU]

escitalopram 10 mg tablet, 28

9432K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	13.58	14.83	^a Esipram [CF]

^B11.72 25.30 14.83 ^a Lexapro [LU]

■ **ESCITALOPRAM**

Restricted benefit

Major depressive disorders

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

escitalopram 20 mg/mL oral liquid, 15 mL

10181W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	37.45	38.70	Lexapro [LU]

■ **FLUOXETINE**

Restricted benefit

Major depressive disorders

Restricted benefit

Obsessive-compulsive disorder

fluoxetine 20 mg capsule, 28

1434L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.19	16.44	^a APO-Fluoxetine [TX] ^a Blooms the Chemist Fluoxetine [IB] ^a FLUOTEX [RF] ^a Fluoxetine-GA [ED] ^a Fluoxetine Sandoz [SZ] ^a Lovan [AL] ^a Zactin [AF]	^a Auscap Aspen [RW] ^a Chem mart Fluoxetine [CH] ^a Fluoxetine AN [EA] ^a Fluoxetine generichealth [GQ] ^a GenRx Fluoxetine [GX] ^a Terry White Chemists Fluoxetine [TW]
			^B 1.18	16.37	16.44	^a Prozac 20 [LY]	

fluoxetine 20 mg tablet, 28

8270G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.19	16.44	^a Lovan 20 Tab [AL]	^a Zactin Tablet [AF]
			^B 1.18	16.37	16.44	^a Prozac Tab [LY]	

■ **FLUVOXAMINE**

Restricted benefit

Major depressive disorders

Restricted benefit

Obsessive-compulsive disorder

fluvoxamine maleate 50 mg tablet, 30

8512B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.14	18.39	^a APO-Fluvoxamine [TX] ^a Fluvoxamine AN [ED] ^a Movox 50 [AL]	^a Faverin 50 [RW] ^a Fluvoxamine GA [EA] ^a Voxam [SZ]
			^B 3.50	20.64	18.39	^a Luvox [GO]	

fluvoxamine maleate 100 mg tablet, 30

8174F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.05	21.30	^a APO-Fluvoxamine [TX] ^a Fluvoxamine AN [ED] ^a Movox 100 [AF]	^a Faverin 100 [RW] ^a Fluvoxamine GA [EA] ^a Voxam [SZ]
			^B 3.50	23.55	21.30	^a Luvox [GO]	

PAROXETINE**Restricted benefit**

Major depressive disorders

Restricted benefit

Obsessive-compulsive disorder

Restricted benefit

Panic disorder

paroxetine 20 mg tablet, 30

2242B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.90	16.15	^a APO-Paroxetine [TX] ^a Extine 20 [RW] ^a Paroxetine AN [EA] ^a Paroxetine Sandoz [SZ] ^a Roxet 20 [DO]	^a Chem mart Paroxetine [CH] ^a GenRx Paroxetine [GX] ^a Paroxetine GH [GQ] ^a Paxtine [AF] ^a Terry White Chemists Paroxetine [TW]
			^B 2.58	17.48	16.15	^a Aropax [AS]	

SERTRALINE**Restricted benefit**

Major depressive disorders

sertraline 100 mg tablet, 30

2237R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.17	14.42	^a APO-Sertraline [TX] ^a Chem mart Sertraline [CH] ^a Sertra 100 [RW] ^a Sertraline generichealth [GQ] ^a Setrona [RA]	^a Auro-Sertraline 100 [DO] ^a Eleva 100 [AF] ^a Sertraline AN [EA] ^a Sertraline Sandoz [SZ] ^a Terry White Chemists Sertraline [TW]
			^B 5.80	18.97	14.42	^a Zoloft [PF]	

sertraline 50 mg tablet, 30

2236Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.17	14.42	^a APO-Sertraline [TX] ^a Chem mart Sertraline [CH] ^a Sertra 50 [RW] ^a Sertraline generichealth [GQ] ^a Setrona [RA]	^a Auro-Sertraline 50 [DO] ^a Eleva 50 [AF] ^a Sertraline AN [EA] ^a Sertraline Sandoz [SZ] ^a Terry White Chemists Sertraline [TW]
			^B 5.80	18.97	14.42	^a Zoloft [PF]	

SERTRALINE**Restricted benefit**

Obsessive-compulsive disorder

Restricted benefit

Panic disorder

Clinical criteria:

- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

sertraline 100 mg tablet, 30

8837D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.17	14.42	^a Auro-Sertraline 100 [DO] ^a Sertraline AN [EA]	^a Eleva 100 [AF]
			^B 5.80	18.97	14.42	^a Zoloft [PF]	

sertraline 50 mg tablet, 30

8836C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.17	14.42	^a Auro-Sertraline 50 [DO]	^a Eleva 50 [AF]
						^a Sertraline AN [EA]	
			^b 5.80	18.97	14.42	^a Zoloft [PF]	

*Monoamine oxidase inhibitors, non-selective***■ PHENELZINE****Caution** This drug is an irreversible monoamine oxidase inhibitor.**Note** Pharmaceutical benefits that have the form phenelzine 15 mg tablet, 60 and pharmaceutical benefits that have the form phenelzine 15 mg tablet, 100 are equivalent for the purposes of substitution.**Restricted benefit**

Depression

Clinical criteria:

- The treatment must be for when all other anti-depressant therapy has failed; OR
- The treatment must be for when all other anti-depressant therapy is inappropriate.

phenelzine 15 mg tablet, 60

11713L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1.7	1	..	*114.87	40.30	^a Nardil [LM]

phenelzine 15 mg tablet, 100

2856H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	80.65	40.30	^a Nardil [LM]

■ TRANLYCYPROMINE**Caution** This drug is an irreversible monoamine oxidase inhibitor.**tranlycypromine 10 mg tablet, 50**

2444P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	49.80	40.30	Parnate [GH]

*Monoamine oxidase A inhibitors***■ MOCLOBEMIDE****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.

Restricted benefit

Major depressive disorders

moclobemide 300 mg tablet, 60

8003F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	27.75	29.00	^a Amira 300 [AF]	^a APO-Moclobemide [TX]
						^a Clobemix [ED]	^a GenRx Moclobemide [GX]
						^a Moclobemide AN [EA]	^a Moclobemide Sandoz [SZ]
			^b 3.00	30.75	29.00	^a Aurorix 300 mg [GO]	

moclobemide 150 mg tablet, 60

1900B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.22	22.47	^a Amira 150 [AF]	^a APO-Moclobemide [TX]
						^a Clobemix [ED]	^a Moclobemide AN [EA]
						^a Moclobemide Sandoz [SZ]	^a Mohexal [HX]
			^b 3.00	24.22	22.47	^a Aurorix [GO]	

*Other antidepressants***■ DESVENLAFAXINE****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.**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.

Restricted benefit

Major depressive disorders

desvenlafaxine 100 mg modified release tablet, 28

10231L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	23.97	25.22	^a Desfax [AF]	^a DESVEN [RW]

^a Desvenlafaxine Actavis [EA] ^a Desvenlafaxine Sandoz [SZ]**NP desvenlafaxine 100 mg modified release tablet, 28**

10245F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	23.97	25.22	^a APO-Desvenlafaxine MR [TX]	^a Desvenlafaxine GH XR [GQ]

desvenlafaxine 100 mg modified release tablet, 28

9367B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	23.97	25.22	^a Pristiq [PF]

■ DESVENLAFAXINE

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 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.

Restricted benefit

Major depressive disorders

desvenlafaxine 50 mg modified release tablet, 28

10234P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	21.65	22.90	^a APO-Desvenlafaxine MR [TX]	^a Desvenlafaxine GH XR [GQ]

desvenlafaxine 50 mg modified release tablet, 28

10241B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	21.65	22.90	^a Desfax [AF] ^a Desvenlafaxine Actavis [EA]	^a DESVEN [RW] ^a Desvenlafaxine Sandoz [SZ]

desvenlafaxine 50 mg modified release tablet, 28

9366Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	21.65	22.90	^a Pristiq [PF]

■ DULOXETINE**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.

Restricted benefit

Major depressive disorders

duloxetine 30 mg enteric capsule, 28

9155W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	15.63	16.88	^a Andepa [EL] ^a Chem mart Duloxetine [CH] ^a Duloxetine AN [EA] ^a Duloxetine Sandoz 30 [SZ] ^a Terry White Chemists Duloxetine [TW]	^a APO-Duloxetine [TX] ^a Duloxecor [CR] ^a Duloxetine Sandoz [HX] ^a DYTREX 30 [RW] ^a Tixel [AL]
			^B 8.00	23.63	16.88	^a Cymbalta [LY]	

duloxetine 60 mg enteric capsule, 28

9156X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	17.40	18.65	^a Andepa [EL] ^a Chem mart Duloxetine [CH] ^a Duloxetine AN [EA] ^a Duloxetine Sandoz 60 [SZ] ^a Terry White Chemists Duloxetine [TW]	^a APO-Duloxetine [TX] ^a Duloxecor [CR] ^a Duloxetine Sandoz [HX] ^a DYTREX 60 [RW] ^a Tixel [AL]
			^B 8.00	25.40	18.65	^a Cymbalta [LY]	

■ LITHIUM CARBONATE**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.

lithium carbonate 250 mg tablet, 200

3059B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	23.58	24.83	Lithicarb [AS]

lithium carbonate 450 mg modified release tablet, 100

8290H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*35.97	37.22	Quilonum SR [AS]

MIANSERIN

Caution Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

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.

Restricted benefit

Severe depression

mianserin hydrochloride 10 mg tablet, 50

1627P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	19.28	20.53	Lumin 10 [AF]

mianserin hydrochloride 20 mg tablet, 50

1628Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	27.93	29.18	Lumin 20 [AF]

MIRTAZAPINE**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.

Restricted benefit

Major depressive disorders

mirtazapine 45 mg orally disintegrating tablet, 30

8857E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.78	21.03	^a Milivin OD 45 [DO] ^a Mirtazapine Sandoz ODT 45 [SZ]	^a Mirtazapine AN ODT [EA]
			^B 4.75	24.53	21.03	^a Remeron SolTab [AF]	

mirtazapine 15 mg tablet, 30

9365X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.88	15.13	^a APO-Mirtazapine [TX] ^a MIRTANZA [RF]	^a Axit 15 [AF] ^a Mirtazapine AN [EA]

mirtazapine 30 mg orally disintegrating tablet, 30

8856D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.00	18.25	^a Milivin OD 30 [DO] ^a Mirtazapine Sandoz ODT 30 [SZ]	^a Mirtazapine AN ODT [EA]
			^B 4.75	21.75	18.25	^a Remeron SolTab [AF]	

mirtazapine 15 mg orally disintegrating tablet, 30

8855C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.62	16.87	^a Milivin OD 15 [DO] ^a Mirtazapine Sandoz ODT 15 [SZ]	^a Mirtazapine AN ODT [EA]
			^B 4.75	20.37	16.87	^a Remeron SolTab [AF]	

mirtazapine 30 mg tablet, 30

8513C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.08	16.33	^a APO-Mirtazapine [TX] ^a Chem mart Mirtazapine [CH] ^a Mirtazapine AN [EA] ^a Mirtazapine Sandoz [SZ] ^a Terry White Chemists Mirtazapine [TW]	^a Axit 30 [AF] ^a MIRTANZA [RF] ^a Mirtazapine GH [GQ] ^a Mirtazon [RW]
			^B 5.00	20.08	16.33	^a Avanza [MK]	

mirtazapine 45 mg tablet, 30

8883M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.48	18.73	^a APO-Mirtazapine [TX] ^a Chem mart Mirtazapine [CH] ^a Mirtazapine AN [EA] ^a Mirtazapine Sandoz [SZ] ^a Terry White Chemists Mirtazapine [TW]	^a Axit 45 [AF] ^a MIRTANZA [RF] ^a Mirtazapine GH [GQ] ^a Mirtazon [RW]

REBOXETINE**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.

Restricted benefit

Major depressive disorders

reboxetine 4 mg tablet, 60

8583R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	38.19	39.44	Edronax [PF]

VENLAFAXINE**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.

Restricted benefit

Major depressive disorders

venlafaxine 150 mg modified release capsule, 28

8302Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.87	17.12	^a APO-Venlafaxine XR [TX] ^a Chem mart Venlafaxine XR [CH] ^a Elaxine SR 150 [ZP] ^a Sandoz Venlafaxine XR [HX] ^a Venlafaxine AN SR [EA] ^a Venlafaxine Sandoz XR [SZ]	^a Blooms the Chemist Venlafaxine XR [IB] ^a Efexor-XR [PF] ^a Enlafax-XR [AF] ^a Terry White Chemists Venlafaxine XR [TW] ^a Venlafaxine generichealth XR [GQ]

venlafaxine 75 mg modified release capsule, 28

8301X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.08	16.33	^a APO-Venlafaxine XR [TX] ^a Chem mart Venlafaxine XR [CH] ^a Elaxine SR 75 [ZP] ^a Sandoz Venlafaxine XR [HX] ^a Venlafaxine AN SR [EA] ^a Venlafaxine Sandoz XR [SZ]	^a Blooms the Chemist Venlafaxine XR [IB] ^a Efexor-XR [PF] ^a Enlafax-XR [AF] ^a Terry White Chemists Venlafaxine XR [TW] ^a Venlafaxine generichealth XR [GQ]

venlafaxine 37.5 mg modified release capsule, 28

8868R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	13.87	15.12	^a Efexor-XR [PF] ^a Venlafaxine AN SR [EA]	^a Elaxine SR 37.5 [ZP]

PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS*Centrally acting sympathomimetics***ARMODAFINIL**

Note This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamfetamine sulfate or modafinil.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Narcolepsy

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a qualified sleep medicine practitioner or neurologist.

Clinical criteria:

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy; OR
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

- (a) a psychiatric disorder;
 - (b) a cardiovascular disorder;
 - (c) a history of substance abuse;
 - (d) glaucoma;
 - (e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.
- The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

- (a) a completed authority prescription form; and
- (b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and
- (c) details of the contraindication or intolerance to dexamfetamine sulfate; and
- (d) either:
 - (i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
 - (ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Authority required

Narcolepsy

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

armodafinil 250 mg tablet, 30

10919Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	250.56	40.30	Nuvigil [TB]

armodafinil 150 mg tablet, 30

10912H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	153.73	40.30	Nuvigil [TB]

armodafinil 50 mg tablet, 30

10922W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*106.33	40.30	Nuvigil [TB]

■ ATOMOXETINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

7876

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a paediatrician or psychiatrist.

Clinical criteria:

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**

- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

Authority required (STREAMLINED)**7890**

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

atomoxetine 10 mg capsule, 28

9092M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*101.05	40.30	^a APO-Atomoxetine [TX] ^a Atomoxetine Amneal [EA] ^a Strattera [LY]	^a ATOMERRA [RW] ^a Atomoxetine Sandoz [SZ]

atomoxetine 80 mg capsule, 28

9289X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	69.69	40.30	^a APO-Atomoxetine [TX] ^a Atomoxetine Amneal [EA] ^a Strattera [LY]	^a ATOMERRA [RW] ^a Atomoxetine Sandoz [SZ]

atomoxetine 40 mg capsule, 28

9095Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*101.05	40.30	^a APO-Atomoxetine [TX] ^a Atomoxetine Amneal [EA] ^a Strattera [LY]	^a ATOMERRA [RW] ^a Atomoxetine Sandoz [SZ]

atomoxetine 60 mg capsule, 28

9096R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*101.05	40.30	^a APO-Atomoxetine [TX] ^a Atomoxetine Amneal [EA] ^a Strattera [LY]	^a ATOMERRA [RW] ^a Atomoxetine Sandoz [SZ]

atomoxetine 18 mg capsule, 28

9093N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*101.05	40.30	^a APO-Atomoxetine [TX] ^a Atomoxetine Amneal [EA] ^a Strattera [LY]	^a ATOMERRA [RW] ^a Atomoxetine Sandoz [SZ]

atomoxetine 100 mg capsule, 28

9290Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	69.69	40.30	^a APO-Atomoxetine [TX] ^a Atomoxetine Amneal [EA] ^a Strattera [LY]	^a ATOMERRA [RW] ^a Atomoxetine Sandoz [SZ]

atomoxetine 25 mg capsule, 28

9094P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*101.05	40.30	^a APO-Atomoxetine [TX] ^a Atomoxetine Amneal [EA] ^a Strattera [LY]	^a ATOMERRA [RW] ^a Atomoxetine Sandoz [SZ]

■ DEXAMFETAMINE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing 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.

Authority required

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

Authority required

Narcolepsy

dexamfetamine sulfate 5 mg tablet, 100

1165H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	20.99	22.24	Aspen Pharma Pty Ltd [QA]

■ LISDEXAMFETAMINE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

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.

Authority required

Attention deficit hyperactivity disorder

Clinical criteria:

- Patient must require continuous coverage over 12 hours.

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

lisdexamfetamine dimesilate 30 mg capsule, 30

10486X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	117.59	40.30	Vyvanse [ZI]

lisdexamfetamine dimesilate 70 mg capsule, 30

10492F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	117.59	40.30	Vyvanse [ZI]

lisdexamfetamine dimesilate 50 mg capsule, 30

10474G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	117.59	40.30	Vyvanse [ZI]

■ METHYLPHENIDATE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing 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.

Authority required

Attention deficit hyperactivity disorder

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours.

methylphenidate hydrochloride 36 mg modified release tablet, 30

2388Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	60.55	40.30	Concerta [JC]

methylphenidate hydrochloride 54 mg modified release tablet, 30

2432B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	69.70	40.30	Concerta [JC]

methylphenidate hydrochloride 27 mg modified release tablet, 30

2172H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	56.42	40.30	Concerta [JC]

methylphenidate hydrochloride 18 mg modified release tablet, 30

2387P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	52.28	40.30	Concerta [JC]

■ METHYLPHENIDATE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing 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.

Authority required

Attention deficit hyperactivity disorder

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours.

methylphenidate hydrochloride 10 mg modified release capsule, 30

3440C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	36.26	37.51	Ritalin LA [NV]

methylphenidate hydrochloride 20 mg modified release capsule, 30

2276T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	45.53	40.30	Ritalin LA [NV]

methylphenidate hydrochloride 40 mg modified release capsule, 30

2283E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	55.52	40.30	Ritalin LA [NV]

methylphenidate hydrochloride 30 mg modified release capsule, 30

2280B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	52.99	40.30	Ritalin LA [NV]

■ METHYLPHENIDATE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing 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.

Authority required

Attention deficit hyperactivity disorder

Treatment must be in accordance with the law of the relevant State or Territory.

methylphenidate hydrochloride 10 mg tablet, 100

8839F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.73	24.98	^a Artige [NM]
			^B 1.61	25.34	24.98	^a Ritalin 10 [NV]

■ MODAFINIL

Note This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamfetamine sulfate or armodafinil.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Narcolepsy

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a qualified sleep medicine practitioner or neurologist.

Clinical criteria:

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy; OR
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

- (a) a psychiatric disorder;
 - (b) a cardiovascular disorder;
 - (c) a history of substance abuse;
 - (d) glaucoma;
 - (e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.
- The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration. The authority application must be made in writing and must include the following:

- (a) a completed authority prescription form; and
 - (b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and
 - (c) details of the contraindication or intolerance to dexamfetamine sulfate; and
 - (d) either:
 - (i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
 - (ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.
- The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Authority required

Narcolepsy

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

modafinil 100 mg tablet, 60

8816B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*247.65	40.30	^a APO-Modafinil [TX] ^a Modafinil AN [EA] ^a Modafinil Mylan [AF] ^a Modavigil [TB]	^a Modafin [RW] ^a Modafinil GH [GQ] ^a Modafinil Sandoz [SZ]

ANTI-DEMENTIA DRUGS

Anticholinesterases

▪ **DONEPEZIL**

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.

Authority required (STREAMLINED)

4219

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

donepezil hydrochloride 5 mg tablet, 28

2532G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	21.54	22.79	^a APO-Donepezil [TX] ^a Aridon 5 [RW] ^a Chem mart Donepezil [CH] ^a Donepezil-DRLA [RZ] ^a Donepezil Sandoz [SZ]	^a Arazil [AF] ^a Aridon APN 5 [RF] ^a Donepezil AN [EA] ^a Donepezil GH [HQ] ^a Terry White Chemists Donepezil [TW]
			^b 3.68	25.22	22.79	^a Aricept [PF]	

donepezil hydrochloride 10 mg tablet, 28

2479L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.54	22.79	^a APO-Donepezil [TX] ^a Aridon 10 [RW] ^a Chem mart Donepezil [CH] ^a Donepezil-DRLA [RZ] ^a Donepezil Sandoz [SZ] ^a Terry White Chemists Donepezil [TW]	^a Arazil [AF] ^a Aridon APN 10 [RF] ^a Donepezil AN [EA] ^a Donepezil GH [HQ] ^a Pharmacor Donepezil 10 [CR]
			^B 9.00	30.54	22.79	^a Aricept [PF]	

■ DONEPEZIL**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.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

donepezil hydrochloride 5 mg tablet, 28

8495D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.54	22.79	^a APO-Donepezil [TX] ^a Aridon 5 [RW] ^a Chem mart Donepezil [CH] ^a Donepezil-DRLA [RZ] ^a Donepezil Sandoz [SZ]	^a Arazil [AF] ^a Aridon APN 5 [RF] ^a Donepezil AN [EA] ^a Donepezil GH [HQ] ^a Terry White Chemists Donepezil [TW]

			^B 3.68	25.22	22.79	^a Aricept [PF]	
donepezil hydrochloride 10 mg tablet, 28							
8496E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.54	22.79	^a APO-Donepezil [TX] ^a Aridon 10 [RW] ^a Chem mart Donepezil [CH] ^a Donepezil-DRLA [RZ] ^a Donepezil Sandoz [SZ] ^a Terry White Chemists Donepezil [TW]	^a Arazil [AF] ^a Aridon APN 10 [RF] ^a Donepezil AN [EA] ^a Donepezil GH [HQ] ^a Pharmacor Donepezil 10 [CR]
			^B 9.00	30.54	22.79	^a Aricept [PF]	

■ GALANTAMINE

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.

Authority required (STREAMLINED)

4219

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

galantamine 16 mg modified release capsule, 28

2537M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	38.24	39.49	^a APO-Galantamine MR [TX] ^a Galantyl [AF] ^a Reminyl [JC]	^a Galantamine AN SR [EA] ^a Gamine XR [RW]

galantamine 8 mg modified release capsule, 28

2463P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.36	34.61	^a APO-Galantamine MR [TX] ^a Galantyl [AF] ^a Reminyl [JC]	^a Galantamine AN SR [EA] ^a Gamine XR [RW]

galantamine 24 mg modified release capsule, 28

2531F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	43.37	40.30	^a APO-Galantamine MR [TX] ^a Galantyl [AF] ^a Reminyl [JC]	^a Galantamine AN SR [EA] ^a Gamine XR [RW]

■ GALANTAMINE

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.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

galantamine 16 mg modified release capsule, 28

8771P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	38.24	39.49	^a APO-Galantamine MR [TX] ^a Galantyl [AF] ^a Reminyl [JC]	^a Galantamine AN SR [EA] ^a Gamine XR [RW]

galantamine 8 mg modified release capsule, 28

8770N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.36	34.61	^a APO-Galantamine MR [TX] ^a Galantyl [AF] ^a Reminyl [JC]	^a Galantamine AN SR [EA] ^a Gamine XR [RW]

galantamine 24 mg modified release capsule, 28

8772Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	43.37	40.30	^a APO-Galantamine MR [TX] ^a Galantyl [AF] ^a Reminyl [JC]	^a Galantamine AN SR [EA] ^a Gamine XR [RW]

■ RIVASTIGMINE

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.

Authority required (STREAMLINED)

4219

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

rivastigmine 9.5 mg/24 hours patch, 30

2551G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	80.98	40.30	^a Exelon Patch 10 [NV]	^a Rivastigmelon Patch 10 [AF]

rivastigmine 3 mg capsule, 56

2493F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.70	40.30	Exelon [NV]

rivastigmine 4.5 mg capsule, 56

2494G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.70	40.30	Exelon [NV]

rivastigmine 6 mg capsule, 56

2526Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.70	40.30	Exelon [NV]

rivastigmine 4.6 mg/24 hours patch, 30

2477J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	80.98	40.30	^a Exelon Patch 5 [NV]	^a Rivastigmelon Patch 5 [AF]

rivastigmine 13.3 mg/24 hours patch, 30

10538P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	80.98	40.30	^a Exelon Patch 15 [NV]	^a Rivastigmelon Patch 15 [AF]

rivastigmine 1.5 mg capsule, 56

2475G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.70	40.30	Exelon [NV]

■ RIVASTIGMINE

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.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**

- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
 - The treatment must be the sole PBS-subsidised therapy for this condition.
- A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

rivastigmine 9.5 mg/24 hours patch, 30

9162F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	80.98	40.30	^a Exelon Patch 10 [NV]	^a Rivastigmelon Patch 10 [AF]

rivastigmine 3 mg capsule, 56

8498G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.70	40.30	Exelon [NV]

rivastigmine 4.5 mg capsule, 56

8499H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.70	40.30	Exelon [NV]

rivastigmine 6 mg capsule, 56

8500J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.70	40.30	Exelon [NV]

rivastigmine 4.6 mg/24 hours patch, 30

9161E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	80.98	40.30	^a Exelon Patch 5 [NV]	^a Rivastigmelon Patch 5 [AF]

rivastigmine 13.3 mg/24 hours patch, 30

10541T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	80.98	40.30	^a Exelon Patch 15 [NV]	^a Rivastigmelon Patch 15 [AF]

rivastigmine 1.5 mg capsule, 56

8497F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.70	40.30	Exelon [NV]

Other anti-dementia drugs

MEMANTINE

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.

Authority required (STREAMLINED)

4214

Moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.
 Clinically meaningful response to treatment is demonstrated in the following areas:
 Patient's quality of life including but not limited to level of independence and happiness;
 Patient's cognitive function including but not limited to memory, recognition and interest in environment;
 Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

memantine hydrochloride 20 mg tablet, 28

2513G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.68	40.30	^a APO-Memantine [TX] ^a Memantine generichealth [GQ]	^a Ebixa [LU]

memantine hydrochloride 10 mg tablet, 56

2492E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.68	40.30	^a APO-Memantine [TX] ^a Memantine generichealth [GQ]	^a Ebixa [LU] ^a Memanxa [RW]

MEMANTINE**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.

Authority required

Moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

memantine hydrochloride 20 mg tablet, 28

9306T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	41.68	40.30	^a APO-Memantine [TX]	^a Ebixa [LU]

^a Memantine generichealth [GQ]

NP	Memantine hydrochloride 10 mg tablet, 56						Brand Name and Manufacturer	Brand Name and Manufacturer
	1956Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$		
		1	5	..	41.68	40.30	^a APO-Memantine [TX]	^a Ebixa [LU]
							^a Memantine generichealth [GQ]	^a Memanxa [RW]

OTHER NERVOUS SYSTEM DRUGS

PARASYMPATHOMIMETICS

Anticholinesterases

■ PYRIDOSTIGMINE

pyridostigmine bromide 180 mg modified release tablet, 50

2608G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*116.93	40.30	Mestinon Timespan [IL]

pyridostigmine bromide 60 mg tablet, 150

1959D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	59.40	40.30	Mestinon [IL]

pyridostigmine bromide 10 mg tablet, 50

2724J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*23.21	24.46	Mestinon [IL]

Choline esters

■ BETHANECHOL

bethanechol chloride 10 mg tablet, 100

1062X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	34.41	35.66	Uro-Carb [YN]

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in nicotine dependence

■ BUPROPION

Note Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

Note The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6881

Nicotine dependence

Treatment Phase: Completion of a short-term (9 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 received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

bupropion hydrochloride 150 mg modified release tablet, 90

8710K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	165.79	40.30	Zyban [AS]

■ BUPROPION

Note Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

Note The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

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.

Authority required (STREAMLINED)

6882

Nicotine dependence

Treatment Phase: Commencement of a short-term (9 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 indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

bupropion hydrochloride 150 mg modified release tablet, 30

8465M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	62.92	40.30	Zyban [AS]

▪ **NICOTINE**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Nicotine dependence

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 indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

nicotine 7 mg/24 hours patch, 28

5573H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	49.36	40.30	Nicotinell Step 3 [ON]

nicotine 21 mg/24 hours patch, 28

3414Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	49.36	40.30	Nicotinell Step 1 [ON]

nicotine 14 mg/24 hours patch, 28

5572G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	49.36	40.30	Nicotinell Step 2 [ON]

▪ **NICOTINE**

Note Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.

Benefit is improved if used in conjunction with a comprehensive support and counselling program.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Nicotine dependence

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition.

nicotine 21 mg/24 hours patch, 28

5571F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	49.36	40.30	Nicotinell Step 1 [ON]

▪ **NICOTINE**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Nicotine dependence

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition.

Note Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

Restricted benefit

Nicotine dependence

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 indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

nicotine 4 mg chewing gum, 216

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11612E	1	2	..	49.36	40.30	Nicotinell [ON]

NP

nicotine 25 mg/16 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10076H	1	2	..	49.36	40.30	nicorette 16hr Invisipatch [JT]

NP

nicotine 4 mg lozenge, 216

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11619M	1	2	..	49.36	40.30	Nicotinell [ON]

NP

nicotine 2 mg chewing gum, 216

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11618L	2	1	..	*68.31	40.30	Nicotinell [ON]

NP

nicotine 21 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5465P	1	2	..	49.36	40.30	Nicabate P [GC]

NP

nicotine 2 mg lozenge, 216

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11617K	1	2	..	49.36	40.30	Nicotinell [ON]

NP

■ VARENICLINE

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.

Authority required (STREAMLINED)

6885

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 received PBS-subsidised treatment with 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.

varenicline 1 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5469W	1	2	..	100.09	40.30	Champix [PF]

NP

■ VARENICLINE

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.

Authority required (STREAMLINED)

7483

Nicotine dependence

Treatment Phase: Continuation of a short-term (12 weeks or 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 received treatment with this drug during this current course of treatment.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

varenicline 1 mg tablet, 56

9129L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*188.71	40.30	Champix [PF]

■ VARENICLINE

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 The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.

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.

Authority required (STREAMLINED)

6871

Nicotine dependence

Treatment Phase: Commencement of a short-term (12 weeks or 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 indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

varenicline 500 microgram tablet [11] (&) varenicline 1 mg tablet [42], 53

9128K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	86.64	40.30	Champix [PF]

Drugs used in alcohol dependence

■ ACAMPROSATE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

5366

Alcohol dependence

Clinical criteria:

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

acamprosate calcium 333 mg enteric tablet, 180

8357W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	127.68	40.30	^a Acamprosate Mylan [AL] ^a Campral [AF]	^a APO-Acamprosate [TX]

■ NALTREXONE

Caution Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.

Note No 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

Alcohol dependence

Clinical criteria:

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

naltrexone hydrochloride 50 mg tablet, 30

8370M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	128.98	40.30	^a APO-Naltrexone [TX]	^a Naltrexone GH [GQ]

OTHER NERVOUS SYSTEM DRUGS

Other nervous system drugs

▪ **RILUZOLE**

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.

Authority required

Amyotrophic lateral sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed by a neurologist, **AND**
- Patient must not have had the disease for more than 5 years, **AND**
- Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

Authority required

Amyotrophic lateral sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

riluzole 50 mg/10 mL oral liquid, 300 mL

11662T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*239.17	40.30	Teglutik [CS]

riluzole 50 mg tablet, 56

8664B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	203.71	40.30	^a APO-Riluzole [TX] ^a Rilutek [SW]	^a Pharmacor Riluzole [CR] ^a Riluzole Sandoz [SZ]

▪ **TETRABENAZINE**

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.

Authority required (STREAMLINED)

5340

Hyperkinetic extrapyramidal disorders

tetrabenazine 25 mg tablet, 112

1330B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	290.59	40.30	iNova Pharmaceuticals (Australia) Pty Ltd [IL]

■ ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

■ ANTIPROTOZOALS

AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES

Other agents against amoebiasis and other protozoal diseases

■ ATOVAQUONE

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.

Authority required (STREAMLINED)

5609

Mild to moderate *Pneumocystis carinii* pneumonia

Population criteria:

- Patient must be an adult, **AND**
- Patient must be intolerant of trimethoprim/sulfamethoxazole therapy.

atovaquone 750 mg/5 mL oral liquid, 210 mL

8300W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	977.24	40.30	Wellvone [AS]

ANTIMALARIALS

Biguanides

■ ATOVAQUONE + PROGUANIL

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Confirmed or suspected *Plasmodium falciparum* malaria

Population criteria:

- Patient must be aged 3 years or older.

Clinical criteria:

- The treatment must be used where quinine containing regimens are inappropriate.

atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12

9439T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	66.55	40.30	Malarone [GK]

Methanolquinolines

■ QUININE

Caution Severe thrombocytopenia has been reported with this drug.

Authority required (STREAMLINED)

5633

Malaria

quinine sulfate dihydrate 300 mg tablet, 50

1975Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	20.30	21.55	Quinate [RW]

Artemisinin and derivatives, combinations

■ ARTEMETHER + LUMEFANTRINE

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Restricted benefit

Confirmed or suspected *Plasmodium falciparum* malaria

Clinical criteria:

- Patient must be unable to swallow a solid dosage form of artemether with lumefantrine.

artemether 20 mg + lumefantrine 120 mg dispersible tablet, 18

5296R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	109.76	40.30	Riamet 20mg/120mg Dispersible [SZ]

■ ARTEMETHER + LUMEFANTRINE

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Restricted benefit

Confirmed or suspected Plasmodium falciparum malaria

artemether 20 mg + lumefantrine 120 mg tablet, 24

9498X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	89.63	40.30	Riamet [SZ]

■ ANTHELMINTICS

ANTITREMATODALS

Quinoline derivatives and related substances

■ PRAZIQUANTEL

Authority required (STREAMLINED)

5659

Schistosomiasis

praziquantel 600 mg tablet, 8

9447F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	39.93	40.30	Biltricide [BN]

NP

ANTINEMATODAL AGENTS

Benzimidazole derivatives

■ ALBENDAZOLE

Authority required (STREAMLINED)

5607

Hydatid disease

Clinical criteria:

- The treatment must be in conjunction with surgery; OR
- The treatment must be used when a surgical cure cannot be achieved; OR
- The treatment must be used when surgery cannot be used.

albendazole 400 mg tablet, 60

8459F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	165.92	40.30	Eskazole [AS]

■ ALBENDAZOLE

Authority required (STREAMLINED)

5680

Tapeworm infestation

albendazole 200 mg tablet, 6

8503M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	35.13	36.38	Zentel [AS]

NP

■ ALBENDAZOLE

Authority required (STREAMLINED)

5817

Whipworm infestation

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

Authority required (STREAMLINED)

5712

Strongyloidiasis

Authority required (STREAMLINED)

5797

Hookworm infestation

albendazole 200 mg tablet, 6

9047E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	35.13	36.38	Zentel [AS]

NP

Tetrahydropyrimidine derivatives

■ PYRANTEL

pyrantel 250 mg tablet, 6

3048K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	23.04	24.29	Anthel 250 [AF]

pyrantel 125 mg tablet, 6

3047J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	17.25	18.50	Anthel 125 [AF]

Avermectines

■ IVERMECTIN

Authority required (STREAMLINED)

4319

Onchocerciasis

ivermectin 3 mg tablet, 4

8359Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	29.06	30.31	Stromectol [MK]

■ IVERMECTIN

Authority required (STREAMLINED)

4328

Strongyloidiasis

Authority required (STREAMLINED)

4565

Crusted (Norwegian) scabies

Clinical criteria:

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must be undergoing topical therapy for this condition; OR
- Patient must have a contraindication to topical treatment.

Population criteria:

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

Authority required (STREAMLINED)

4566

Human sarcoptic scabies

Clinical criteria:

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; OR
- Patient must have a contraindication to topical treatment.

Population criteria:

- Patient must weigh 15 kg or over, **AND**
- Patient must be 5 years of age or older.

Note This drug is not PBS-subsidised for first line treatment of typical scabies.

ivermectin 3 mg tablet, 4

2868Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*46.65	40.30	Stromectol [MK]

■ ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

ECTOPARASITICIDES, INCL. SCABICIDES

Pyrethrines, incl. synthetic compounds

■ PERMETHRIN

permethrin 5% cream, 30 g

3054R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	18.79	20.04	Lyclear [JT]

■ RESPIRATORY SYSTEM

■ NASAL PREPARATIONS

DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

Other nasal preparations

■ MUPIROCIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6647

Staphylococcus aureus infection

Clinical criteria:

- Patient must have nasal colonisation with the bacteria.

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

mupirocin 2% (20 mg/g) ointment, 3 g

9440W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	25.00	26.25	Bactroban [GK]

■ DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

ADRENERGICS, INHALANTS

Selective beta-2-adrenoreceptor agonists

■ FORMOTEROL (EFORMOTEROL)

Restricted benefit

Asthma

Clinical criteria:

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations

8239P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	25.59	26.84	Oxis Turbuhaler [AP]

formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

8240Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	32.68	33.93	Oxis Turbuhaler [AP]

formoterol (eformoterol) fumarate dihydrate 12 microgram powder for inhalation, 60 capsules

8136F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	33.32	34.57	Foradile [SZ]

■ INDACATEROL

Note This drug is not PBS-subsidised for the treatment of asthma.

Note The treatment must not be used in combination with an ICS/LABA, or LAMA/LABA

Note A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note An ICS/LABA includes budesonide/formoterol, fluticasone/salmeterol, or fluticasone/vilanterol

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

indacaterol 150 microgram powder for inhalation, 30 capsules

5134F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.81	40.30	Onbrez [NV]

indacaterol 300 microgram powder for inhalation, 30 capsules

5137J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.81	40.30	Onbrez [NV]

■ SALBUTAMOL

salbutamol 100 microgram/actuation inhalation, 200 actuations

8288F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*19.87	21.12	^a Asmol CFC-free [AL]
			^B 3.66	*23.53	21.12	^a Ventolin CFC-free [GK]

■ SALBUTAMOL

Restricted benefit

Bronchospasm

Clinical criteria:

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

salbutamol 100 microgram/actuation breath activated inhalation, 200 actuations

8354Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*39.47	40.30	Airomir Autohaler [IL]

■ SALBUTAMOL

Note Pharmaceutical benefits that have a 30 x 2 pack size and a 20 x 3 pack size are equivalent for the purposes of substitution.

Restricted benefit

Asthma

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

2001H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.91	21.16	^a APO-Salbutamol [TX]	^a Salbutamol Actavis [EA]
						^a Salbutamol AN [ED]	^a Salbutamol Cipla [LR]
			^B 0.50	*20.41	21.16	^a Asmol 5 uni-dose [AF]	

salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

2000G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.49	20.74	^a APO-Salbutamol [TX]	^a Salbutamol Actavis [EA]
						^a Salbutamol AN [ED]	^a Salbutamol Cipla [LR]
			^B 0.50	*19.99	20.74	^a Asmol 2.5 uni-dose [AF]	

salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

11130T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	^B 5.01	*24.49	20.73	^a Ventolin Nebules [GK]

salbutamol 5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

11095Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	^B 4.98	*24.88	21.15	^a Ventolin Nebules [GK]

■ SALMETEROL**Restricted benefit**

Asthma

Clinical criteria:

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8141L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	33.32	34.57	Serevent Accuhaler [GK]

■ TERBUTALINE**terbutaline sulfate 500 microgram/actuation powder for inhalation, 100 actuations**

2817G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*19.55	20.80	Bricanyl Turbuhaler [AP]

Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics

■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)**4380**

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

Population criteria:

- Patient must be aged 12 years or over.

budesonide 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

8796Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	48.06	40.30	Symbicort Turbuhaler 100/6 [AP]

■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)**Note** This product is not indicated for the initiation of treatment in asthma**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.**Authority required (STREAMLINED)****4397**

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

Population criteria:

- Patient must be aged 12 years or over.

budesonide 50 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

10024N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*46.25	40.30	Symbicort Rapihaler 50/3 [AP]

budesonide 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

10015D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*49.47	40.30	Symbicort Rapihaler 100/3 [AP]

■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.**Note** Patient must be aged 18 years or older.**Note** This product is not indicated for the initiation of treatment in asthma**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.**Authority required (STREAMLINED)****7970**

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR

- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

11273H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	44.79	40.30	^a DuoResp Spiromax [TB]

■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)

Note Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Note Patient must be aged 12 years or over.

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

7970

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

8625Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	44.79	40.30	^a Symbicort Turbuhaler 200/6 [AP]

■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

4404

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

Note Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Authority required (STREAMLINED)

4689

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

10018G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*71.43	40.30	Symbicort Rapihaler 200/6 [AP]

■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)

Note Pharmaceutical benefits that have the brand DuoResp Spiromax 400/12 powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 400/12 powder for inhalation, 2 x 60 actuations are equivalent for the purposes of substitution.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)**7979**

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Note Patient must be aged 18 years or older.

Note Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Authority required (STREAMLINED)**4689**

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LABA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations

11301T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	64.06	40.30	^a DuoResp Spiromax [TB]

■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)

Note Pharmaceutical benefits that have the brand DuoResp Spiromax 400/12 powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 400/12 powder for inhalation, 2 x 60 actuations are equivalent for the purposes of substitution.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)**7979**

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Note Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note Patient must be aged 18 years or older.

Authority required (STREAMLINED)**4689**

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**

- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations

8750M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	64.06	40.30	^a Symbicort Turbuhaler 400/12 [AP]

FLUTICASONE + FORMOTEROL (EFORMOTEROL)

Note Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

4395

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

fluticasone propionate 125 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations

10007Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	45.16	40.30	flutiform 125/5 [MF]

fluticasone propionate 250 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 10 microgram/actuation inhalation, 120 actuations

10008R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	60.07	40.30	flutiform 250/10 [MF]

fluticasone propionate 50 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations

2827T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	37.30	38.55	flutiform 50/5 [MF]

FLUTICASONE + SALMETEROL

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

4930

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 4 years or older.

fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8431R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	48.64	40.30	Seretide Accuhaler 250/50 [GK]

fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8430Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	41.95	40.30	Seretide Accuhaler 100/50 [GK]

fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations

8518H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	48.64	40.30	^a Fluticasone + Salmeterol Cipla 125/25 [LR]	^a Pavtide [GC]
						^a SalplusF Inhaler 125/25 [SZ]	^a Seretide MDI 125/25 [GK]

fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations

8517G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	41.95	40.30	Seretide MDI 50/25 [GK]

■ FLUTICASONE + SALMETEROL

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)**4930**

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 4 years or older.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Authority required (STREAMLINED)**4689**

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations

8519J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	61.78	40.30	^a Fluticasone + Salmeterol Cipla 250/25 [LR]	^a Pavtide [GC]
						^a SalplusF Inhaler 250/25 [SZ]	^a Seretide MDI 250/25 [GK]

fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8432T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	61.78	40.30	Seretide Accuhaler 500/50 [GK]

■ FLUTICASONE FUROATE + VILANTEROL

Note This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)**4731**

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

11129R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	72.01	40.30	Breo Ellipta 200/25 [GK]

■ FLUTICASONE FUROATE + VILANTEROL

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)**4711**

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

Note This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Authority required (STREAMLINED)**4689**

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

11124L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	56.51	40.30	Breo Ellipta 100/25 [GK]

Adrenergics in combination with anticholinergics incl. triple combinations with corticosteroids

■ ACLIDINIUM + FORMOTEROL (EFORMOTEROL)

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)**7798**

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

aclidinium 340 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

10565C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	87.77	40.30	Brimica Genuair [FK]

FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL

Note Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au/>); the assessment and adherence to correct technique should be documented in the patient's medical records.

Note Diagnosis of COPD should be confirmed with spirometry.

Note This product is not PBS-subsidised for the treatment of asthma or the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LABA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclomethasone or ciclesonide.

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.

Authority required (STREAMLINED)**7651**

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, AND
- Patient must have a history of repeated exacerbations with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA), or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LABA, LABA and an ICS for this condition.

fluticasone furoate 100 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

11379X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	97.50	40.30	Trelegy Ellipta 100/62.5/25 [GK]

INDACATEROL + GLYCOPYRRONIUM

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LABA, LABA, or SAMA

Note A LABA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)**7798**

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LABA and a LABA.

indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules

10156M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	88.88	40.30	ultibro breezhaler 110/50 [NV]

TIOTROPIUM + OLODATEROL

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LABA, LABA, or SAMA

Note A LABA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

7798

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations

10557P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	83.39	40.30	Spolto Respimat [BY]

▪ **UMECLIDINIUM + VILANTEROL**

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

7798

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

10188F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	92.95	40.30	Anoro Ellipta 62.5/25 [GK]

OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

Glucocorticoids

▪ **BECLOMETASONE**

beclometasone dipropionate 100 microgram/actuation inhalation, 200 actuations

8407L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	30.59	31.84	Qvar 100 [IL]

beclometasone dipropionate 50 microgram/actuation inhalation, 200 actuations

8406K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	20.58	21.83	Qvar 50 [IL]

▪ **BECLOMETASONE**

Restricted benefit

Asthma

Clinical criteria:

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

beclometasone dipropionate 50 microgram/actuation breath activated inhalation, 200 actuations

8408M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	26.63	27.88	Qvar 50 Autohaler [IL]

beclomethasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations

8409N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	34.59	35.84	Qvar 100 Autohaler [IL]

■ BUDESONIDE**budesonide 200 microgram/actuation powder for inhalation, 200 actuations**

2071B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	28.89	30.14	Pulmicort Turbuhaler [AP]

budesonide 100 microgram/actuation powder for inhalation, 200 actuations

2070Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	23.44	24.69	Pulmicort Turbuhaler [AP]

budesonide 400 microgram/actuation powder for inhalation, 200 actuations

2072C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	39.85	40.30	Pulmicort Turbuhaler [AP]

■ BUDESONIDE**Authority required (STREAMLINED)****6340**

Severe chronic asthma

Clinical criteria:

- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules

2065Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	33.69	34.94	Pulmicort Respules [AP]

budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules

2066R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	42.41	40.30	Pulmicort Respules [AP]

■ CICLESONIDE**ciclesonide 80 microgram/actuation inhalation, 120 actuations**

8853Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	26.15	27.40	Alvesco 80 [AP]

ciclesonide 160 microgram/actuation inhalation, 120 actuations

8854B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	38.26	39.51	Alvesco 160 [AP]

■ FLUTICASONE**fluticasone propionate 500 microgram/actuation powder for inhalation, 60 actuations**

8149X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	42.45	40.30	Flixotide Accuhaler [GK]

fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations

8148W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	28.31	29.56	Flixotide Accuhaler [GK]

fluticasone propionate 125 microgram/actuation inhalation, 120 actuations

8345F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	28.31	29.56	^a Flixotide [GK]	^a Fluticasone Cipla Inhaler [LR]

fluticasone propionate 50 microgram/actuation inhalation, 120 actuations

8516F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	18.89	20.14	Flixotide Junior [GK]

fluticasone propionate 250 microgram/actuation inhalation, 120 actuations

8346G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	1	..	42.45	40.30	^a Flixotide [GK]	^a Fluticasone Cipla Inhaler [LR]

fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations

8147T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	18.89	20.14	Flixotide Junior Accuhaler [GK]

FLUTICASONE FUROATE**fluticasone furoate 100 microgram/actuation powder for inhalation, 30 actuations**

11719T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	28.31	29.56	Arnuity Ellipta [GK]

fluticasone furoate 200 microgram/actuation powder for inhalation, 30 actuations

11729H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	42.45	40.30	Arnuity Ellipta [GK]

Anticholinergics**ACLIDINIUM**

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

aclidinium 322 microgram/actuation inhalation: powder for, 60 actuations

10124W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	62.36	40.30	Bretaris Genuair [FK]

GLYCOPYRRONIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

glycopyrronium 50 microgram powder for inhalation, 30 capsules

10059K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.81	40.30	seebri breezhaler [NV]

IPRATROPIUM**ipratropium bromide monohydrate 21 microgram/actuation inhalation, 200 actuations**

8671J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*35.33	36.58	Atrovent [BY]

IPRATROPIUM**Restricted benefit**

Asthma

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

ipratropium bromide 500 microgram/mL inhalation solution, 30 x 1 mL ampoules

8238N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*30.67	31.92	^a Aeron 500 [QA]	^a APO-Ipratropium [TX]

- **TIOTROPIUM**

Restricted benefit

Clinical criteria:

Clinical criteria:

- Patient must have experienced at least one severe exacerbation, which has required documented use of systemic corticosteroids, in the previous 12 months while receiving optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

Population criteria:

- Patient must be aged 18 years or older.
- Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

TIOTROPIUM

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 Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

8606

Severe asthma

Treatment criteria:

- Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists.

Clinical criteria:

- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; OR
- Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.
- Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative

807

■ **TIOTROPIUM**

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease

Treatment Phase: Long-term maintenance treatment

tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

10509D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	52.80	40.30	Spiriva Respimat [BY]

■ **TIOTROPIUM**

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

tiotropium 18 microgram powder for inhalation, 30 capsules

8626B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	52.80	40.30	Spiriva [BY]

■ **UMECLIDINIUM**

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations

10187E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	62.36	40.30	Incruse Ellipta [GK]

Antiallergic agents, excl. corticosteroids

■ **CROMOGLYCAT****sodium cromoglycate 1 mg/actuation inhalation, 200 actuations**

8767K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	35.03	36.28	Intal CFC-Free [SW]

sodium cromoglycate 5 mg/actuation inhalation, 112 actuations

8334P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	39.21	40.30	Intal Forte CFC-Free [SW]

■ **NEDOCROMIL****nedocromil sodium 2 mg/actuation inhalation, 112 actuations**

8365G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	35.10	36.35	Tilade CFC-Free [SW]

ADRENERGICS FOR SYSTEMIC USE

Alpha- and beta-adrenoreceptor agonists

■ ADRENALINE (EPINEPHRINE)

adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

1016L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	21.14	22.39	Link Medical Products Pty Ltd [LM]

adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

5004J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	21.14	22.39	Link Medical Products Pty Ltd [LM]

■ ADRENALINE (EPINEPHRINE)

Note The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

Note Authority approvals will be limited to a maximum quantity of 2 auto-injectors at any one time.

Note No applications for repeats will be authorised.

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply.

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug.

adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device

8697R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	83.72	40.30	^a Adrenaline Jr Mylan [AF]	^a EpiPen Jr. [AL]

adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device

8698T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	83.72	40.30	^a Adrenaline Mylan [AF]	^a EpiPen [AL]

Selective beta-2-adrenoreceptor agonists

■ SALBUTAMOL

salbutamol 2 mg/5 mL oral liquid, 150 mL

1103C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*25.21	26.46	Ventolin [GK]

■ TERBUTALINE

terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules

1034K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	28.55	29.80	Bricanyl [AP]

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Xanthines

■ THEOPHYLLINE

Caution Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

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.

theophylline 133.3 mg/25 mL oral liquid, 500 mL

2614N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	16.26	17.51	Nuelin [IL]

theophylline 250 mg modified release tablet, 100

2634P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.35	17.60	Nuelin-SR 250 [IL]

theophylline 200 mg modified release tablet, 100

8230E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	15.53	16.78	Nuelin-SR 200 [IL]

theophylline 300 mg modified release tablet, 100

8231F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.34	18.59	Nuelin-SR 300 [IL]

Leukotriene receptor antagonists

■ MONTELUKAST

Note This drug is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

Note This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6666

Asthma

Treatment Phase: First-line prevention

Population criteria:

- Patient must be aged 2 to 5 years inclusive.

Clinical criteria:

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

montelukast 4 mg chewable tablet, 28

8627C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.63	19.88	^a APO-Montelukast [TX] ^a Lukair [AL] ^a Montelukast APOTEX [GX] ^a Montelukast Sandoz 4 [SZ]	^a Auro-Montelukast Tabs 4 [DO] ^a Montelukast AN [EA] ^a Montelukast GH [GQ] ^a Respikast 4 [RW]
			^b 3.00	21.63	19.88	^a Singulair [MK]	

■ MONTELUKAST

Note This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6674

Asthma

Treatment Phase: First-line prevention

Clinical criteria:

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

Population criteria:

- Patient must be aged 6 to 14 years inclusive.

Authority required (STREAMLINED)

7781

Asthma

Treatment Phase: Prevention of condition

Clinical criteria:

- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; OR
- The treatment must be an alternative to adding formoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

Population criteria:

- Patient must be aged 6 to 14 years inclusive.

montelukast 5 mg chewable tablet, 28

8628D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.21	19.46	^a APO-Montelukast [TX]	^a Auro-Montelukast Tabs 5 [DO]
						^a Lukair [AL]	^a Montelukast AN [EA]
						^a Montelukast APOTEX [GX]	^a Montelukast GH [GQ]
						^a Montelukast Sandoz 5 [SZ]	^a Respikast 5 [RW]
			^B 3.00	21.21	19.46	^a Singulair [MK]	

COUGH AND COLD PREPARATIONS

COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

Opium alkaloids and derivatives

CODEINE

codeine phosphate hemihydrate 30 mg tablet, 20

1214X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	20.06	21.31	Aspen Pharma Pty Ltd [QA]

ANTI HISTAMINES FOR SYSTEMIC USE

ANTI HISTAMINES FOR SYSTEMIC USE

Phenothiazine derivatives

PROMETHAZINE

promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules

1948M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*35.07	36.32	Hospira Pty Limited [PF]

SENSORY ORGANS

OPHTHALMOLOGICALS

ANTIINFECTIVES

Antibiotics

AZITHROMYCIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Trachoma

azithromycin 200 mg/5 mL powder for oral liquid, 15 mL

8201P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	#26.75	28.36	Zithromax [PF]

azithromycin 500 mg tablet, 2

8336R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	15.76	17.01	^a APO-Azithromycin [TX]	^a Azithromycin Mylan [AF]
						^a Azithromycin Sandoz [SZ]	^a Chem mart Azithromycin [CH]
						^a Terry White Chemists	^a ZITHRO [RW]
						Azithromycin [TW]	
						^a Zithromax [PF]	

CHLORAMPHENICOL

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

SENSORY ORGANS

chloramphenicol 0.5% eye drops, 10 mL

11112W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP MW	‡1	2	..	15.46	16.71	Chlorsig [QA]

■ GENTAMICIN

Restricted benefit

Perioperative use in ophthalmic surgery

Restricted benefit

Suspected Pseudomonal eye infection

gentamicin 0.3% eye drops, 5 mL

5566Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	2	..	21.80	23.05	Genoptic [AG]

■ GENTAMICIN

Restricted benefit

Invasive ocular infection

Restricted benefit

Perioperative use in ophthalmic surgery

Restricted benefit

Suspected Pseudomonal eye infection

gentamicin 0.3% eye drops, 5 mL

1441W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	21.80	23.05	Genoptic [AG]

■ TOBRAMYCIN

Restricted benefit

Perioperative use in ophthalmic surgery

Restricted benefit

Suspected Pseudomonal eye infection

tobramycin 0.3% eye ointment, 3.5 g

5570E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	..	..	24.66	25.91	Tobrex [NV]

tobramycin 0.3% eye drops, 5 mL

5569D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	2	..	22.10	23.35	Tobrex [NV]

■ TOBRAMYCIN

Restricted benefit

Invasive ocular infection

Restricted benefit

Perioperative use in ophthalmic surgery

Restricted benefit

Suspected Pseudomonal eye infection

tobramycin 0.3% eye ointment, 3.5 g

2329N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	24.66	25.91	Tobrex [NV]

tobramycin 0.3% eye drops, 5 mL

2328M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	22.10	23.35	Tobrex [NV]

Antivirals

■ ACICLOVIR

Restricted benefit

Herpes simplex keratitis

aciclovir 3% eye ointment, 4.5 g

11654J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	..	..	64.70	40.30	^a AciVision [DZ]

aciclovir 3% eye ointment, 4.5 g

5501M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	..	..	38.47	39.72	^a Zovirax [GK]

■ ACICLOVIR

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Herpes simplex keratitis

aciclovir 3% eye ointment, 4.5 g

1002R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	38.47	39.72	^a Zovirax [GK]

aciclovir 3% eye ointment, 4.5 g

11652G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	64.70	40.30	^a AciVision [DZ]

Fluoroquinolones

■ CIPROFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

ciprofloxacin 0.3% eye drops, 5 mL

1217C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*30.67	31.92	^a CiloQuin [NM]
			^B 4.36	*35.03	31.92	^a Ciloxan [NV]

■ CIPROFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

ciprofloxacin 0.3% eye drops, 5 mL

5564W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	..	..	*30.67	31.92	^a CiloQuin [NM]
			^B 4.36	*35.03	31.92	^a Ciloxan [NV]

■ OFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

ofloxacin 0.3% eye drops, 5 mL

5567B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	..	..	*31.89	33.14	Ocuflox [AG]

■ OFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

ofloxacin 0.3% eye drops, 5 mL

8383F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*31.89	33.14	Ocuflox [AG]

ANTIINFLAMMATORY AGENTS

Corticosteroids, plain

■ DEXAMETHASONE

dexamethasone 0.1% eye drops, 5 mL

1288T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	15.12	16.37	Maxidex [NV]

■ DEXAMETHASONE

Authority required

Non-infectious posterior segment uveitis

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 6/12 or worse in the eye proposed for treatment, secondary to vitreous haze or macular oedema, **AND**
- Patient must have unilateral, asymmetric or bilateral flare-up where systemic treatment or further intensification of systemic treatment is not clinically indicated.

dexamethasone 700 microgram implant, 1

11317P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1355.18	40.30	Ozurdex [AG]

■ DEXAMETHASONE

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

dexamethasone 0.1% eye drops, 5 mL

5565X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	..	..	15.12	16.37	Maxidex [NV]

■ DEXAMETHASONE

Note Special Pricing Arrangements apply.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must be unsuitable for treatment with VEGF inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

dexamethasone 700 microgram implant, 1

10943Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1355.18	40.30	Ozurdex [AG]

▪ **DEXAMETHASONE**

Note No 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

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Authority required

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Authority required

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

dexamethasone 700 microgram implant, 1

11469P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	1355.18	40.30	Ozurdex [AG]

▪ **FLUOROMETHOLONE**

fluorometholone 0.1% eye drops, 5 mL

1204J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	14.44	15.69	FML Liquifilm [AG]

▪ **FLUOROMETHOLONE**

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

fluorometholone 0.1% eye drops, 5 mL

5513E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	14.44	15.69	FML Liquifilm [AG]

■ FLUOROMETHOLONE ACETATE

fluorometholone acetate 0.1% eye drops, 5 mL

1438Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	14.44	15.69	Flarex [NV]

■ FLUOROMETHOLONE ACETATE

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

fluorometholone acetate 0.1% eye drops, 5 mL

5533F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	..	..	14.44	15.69	Flarex [NV]

■ HYDROCORTISONE ACETATE

hydrocortisone acetate 1% eye ointment, 5 g

2441L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	16.93	18.18	Hycor [QA]

■ HYDROCORTISONE ACETATE

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

hydrocortisone acetate 1% eye ointment, 5 g

5516H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	..	..	16.93	18.18	Hycor [QA]

Corticosteroids and mydriatics in combination

■ PREDNISOLONE ACETATE + PHENYLEPHRINE

Restricted benefit

Corneal grafts

Restricted benefit

Uveitis

prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL

3112T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	28.35	29.60	Prednefrin Forte [AG]

■ PREDNISOLONE ACETATE + PHENYLEPHRINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Uveitis

prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL

5568C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	..	..	28.35	29.60	Prednefrin Forte [AG]

ANTIGLAUCOMA PREPARATIONS AND MIOTICS

Sympathomimetics in glaucoma therapy1)

■ APRACLOPIDINE

Restricted benefit

Intra-ocular pressure

Clinical criteria:

- The treatment must be for short-term reduction of intra-ocular pressure, **AND**
- Patient must already be on maximally tolerated anti-glaucoma therapy.

apraclonidine 0.5% eye drops, 10 mL

8083K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	36.54	37.79	Iopidine 0.5% [NV]

■ BRIMONIDINE

brimonidine tartrate 0.15% eye drops, 5 mL

5298W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	23.41	24.66	Alphagan P 1.5 [AG]

brimonidine tartrate 0.2% eye drops, 5 mL

8351M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	23.41	24.66	^a Enidin [PE]
			^B 1.42	24.83	24.66	^a Alphagan [AG]

■ BRIMONIDINE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

brimonidine tartrate 0.15% eye drops, 5 mL

5563T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	23.41	24.66	Alphagan P 1.5 [AG]

brimonidine tartrate 0.2% eye drops, 5 mL

5534G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	23.41	24.66	^a Enidin [PE]
			^B 1.42	24.83	24.66	^a Alphagan [AG]

■ BRIMONIDINE + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL

8826M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	28.53	29.78	Combigan [AG]

■ BRIMONIDINE + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL

5535H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	28.53	29.78	Combigan [AG]

Parasympathomimetics

■ PILOCARPINE

pilocarpine hydrochloride 1% eye drops, 15 mL

2595N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	16.79	18.04	Isopto Carpine [NV]

pilocarpine hydrochloride 2% eye drops, 15 mL

2596P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	17.88	19.13	Isopto Carpine [NV]

pilocarpine hydrochloride 4% eye drops, 15 mL

2598R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	20.36	21.61	Isopto Carpine [NV]

■ PILOCARPINE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

pilocarpine hydrochloride 1% eye drops, 15 mL

5536J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	16.79	18.04	Isopto Carpine [NV]

pilocarpine hydrochloride 2% eye drops, 15 mL

5537K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	17.88	19.13	Isopto Carpine [NV]

pilocarpine hydrochloride 4% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5538L	±1	5	..	20.36	21.61	Isopto Carpine [NV]

OP

Carbonic anhydrase inhibitors
ACETAZOLAMIDE
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.

acetazolamide 250 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1004W	1	3	..	25.01	26.26	Diamox [RW]

NP

BRINZOLAMIDE
brinzolamide 1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8483L	±1	5	..	25.70	26.95	^a BrinzoQuin [NM]
			^B 4.78	30.48	26.95	^a Azopt [NV]

BRINZOLAMIDE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

brinzolamide 1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5540N	±1	5	..	25.70	26.95	^a BrinzoQuin [NM]
			^B 4.78	30.48	26.95	^a Azopt [NV]

OP

BRINZOLAMIDE + BRIMONIDINE
Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10536M	±1	5	..	28.04	29.29	Simbrinza 1%/0.2% [NV]

BRINZOLAMIDE + BRIMONIDINE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10547D	±1	5	..	28.04	29.29	Simbrinza 1%/0.2% [NV]

OP

BRINZOLAMIDE + TIMOLOL
Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brinzolamide 1% + timolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3438Y	±1	5	..	29.27	30.52	Azarga [NV]

■ BRINZOLAMIDE + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brinzolamide 1% + timolol 0.5% eye drops, 5 mL

5562R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	29.27	30.52	Azarga [NV]

■ DORZOLAMIDE

dorzolamide 2% eye drops, 5 mL

8488R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	5	..	19.33	20.58	^a APO-Dorzolamide [TX] ^a Trusopt [MF]	^a Trusamide [QA]

■ DORZOLAMIDE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

dorzolamide 2% eye drops, 5 mL

5541P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±1	5	..	19.33	20.58	^a APO-Dorzolamide [TX] ^a Trusopt [MF]	^a Trusamide [QA]

■ DORZOLAMIDE + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

dorzolamide 2% + timolol 0.5% eye drops, 5 mL

8567X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	5	..	22.07	23.32	^a APO-Dorzolamide/Timolol 20/5 [TX] ^a DORZOLAMIDE/TIMOLOL AN 20/5 [JU] ^B 1.00 23.07 23.32 ^a Cosopt [MF]	^a Cosdor [QA]

■ DORZOLAMIDE + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

dorzolamide 2% + timolol 0.5% eye drops, 5 mL

5542Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±1	5	..	22.07	23.32	^a APO-Dorzolamide/Timolol 20/5 [TX] ^a DORZOLAMIDE/TIMOLOL AN 20/5 [JU] ^B 1.00 23.07 23.32 ^a Cosopt [MF]	^a Cosdor [QA]

Beta blocking agents1)

■ BETAXOLOL

betaxolol 0.5% eye drops, 5 mL

2825Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	18.74	19.99	^a BetoQuin [NM] ^B 4.76 23.50 19.99 ^a Betoptic [NV]

■ BETAXOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

betaxolol 0.5% eye drops, 5 mL

5544T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	18.74	19.99	^a BetoQuin [NM]
			^B 4.76	23.50	19.99	^a Betoptic [NV]

■ TIMOLOLOL
timolol 0.25% eye drops, 2.5 mL

1925H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	17.08	18.33	Timoptol XE [MF]

timolol 0.5% eye drops, 2.5 mL

1926J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	17.26	18.51	Timoptol XE [MF]

timolol 0.5% eye drops, 5 mL

1279H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	17.20	18.45	Timoptol [MF]

■ TIMOLOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

timolol 0.25% eye drops, 2.5 mL

5549C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	17.08	18.33	Timoptol XE [MF]

timolol 0.5% eye drops, 2.5 mL

5550D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	17.26	18.51	Timoptol XE [MF]

timolol 0.5% eye drops, 5 mL

5548B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	17.20	18.45	Timoptol [MF]

Prostaglandin analogues¹⁾
■ BIMATOPROST
bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses

10046R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	32.40	33.65	Lumigan PF [AG]

bimatoprost 0.03% eye drops, 3 mL

8620Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	5	..	36.40	37.65	^a APO-Bimatoprost [TX] ^a Bimtop [QA]	^a Bimatoprost Sandoz [SZ] ^a Lumigan [AG]

■ BIMATOPROST

Note For prescribing in accordance with Optometry Board of Australia guidelines.

bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses

10053D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	32.40	33.65	Lumigan PF [AG]

bimatoprost 0.03% eye drops, 3 mL

5551E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	5	..	36.40	37.65	^a APO-Bimatoprost [TX] ^a Bimtop [QA]	^a Bimatoprost Sandoz [SZ] ^a Lumigan [AG]

■ BIMATOPROST + TIMOLOLOL
Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses

10107Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	37.19	38.44	Ganfort PF 0.3/5 [AG]

■ BIMATOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

9464D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	40.85	40.30	Ganfort 0.3/5 [AG]

■ BIMATOPROST + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

5558M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	40.85	40.30	Ganfort 0.3/5 [AG]

bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses

10108B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	37.19	38.44	Ganfort PF 0.3/5 [AG]

■ LATANOPROST

latanoprost 0.005% eye drops, 2.5 mL

8243W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	5	..	17.31	18.56	^a APO-Latanoprost [TX] ^a Latanoprost Actavis [EA] ^a Xalaprost [QA]	^a Lanpro [JU] ^a Latanoprost Sandoz [SZ] ^a Xalatan [PF]

■ LATANOPROST

Note For prescribing in accordance with Optometry Board of Australia guidelines.

latanoprost 0.005% eye drops, 2.5 mL

5552F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	5	..	17.31	18.56	^a APO-Latanoprost [TX] ^a Latanoprost Actavis [EA] ^a Xalaprost [QA]	^a Lanpro [JU] ^a Latanoprost Sandoz [SZ] ^a Xalatan [PF]

■ LATANOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL

8895E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	5	..	21.76	23.01	^a APO-Latanoprost/Timolol 0.05/5 [TX] ^a Latanoprost/timolol AN 50/5 [JO] ^a Xalacom [PF]	^a Lantim [JU] ^a Latanoprost/Timolol Sandoz 50/5 [SZ] ^a Xalamol 50/5 [QA]

■ LATANOPROST + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL

5553G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±1	5	..	21.76	23.01	^a APO-Latanoprost/Timolol 0.05/5 [TX]	^a Lantim [JU]
						^a Latanoprost/timolol AN 50/5 [JO]	^a Latanoprost/Timolol Sandoz 50/5 [SZ]
						^a Xalacom [PF]	^a Xalamol 50/5 [QA]

▪ **TAFLUPROST**

tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses

2755B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	34.11	35.36	Saflutan [MF]

▪ **TAFLUPROST**

Note For prescribing in accordance with Optometry Board of Australia guidelines.

tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses

2748P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	34.11	35.36	Saflutan [MF]

▪ **TRAVOPROST**

travoprost 0.004% eye drops, 2.5 mL

8597L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	36.84	38.09	Travatan [NV]

▪ **TRAVOPROST**

Note For prescribing in accordance with Optometry Board of Australia guidelines.

travoprost 0.004% eye drops, 2.5 mL

5554H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	36.84	38.09	Travatan [NV]

▪ **TRAVOPROST + TIMOLOL**

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

9057Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	41.30	40.30	Duotrav [NV]

▪ **TRAVOPROST + TIMOLOL**

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

5555J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	41.30	40.30	Duotrav [NV]

MYDRIATICS AND CYCLOPLEGICS

Anticholinergics

■ **ATROPINE SULFATE**

atropine sulfate monohydrate 1% eye drops, 15 mL

1093M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	22.33	23.58	Atropt [QA]

OCULAR VASCULAR DISORDER AGENTS

Antineovascularisation agents

■ **AFLIBERCEPT**

Note No 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

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

10505X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1096.21	40.30	Eylea [BN]

■ **AFLIBERCEPT**

Note Special Pricing Arrangements apply.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Note Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No 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

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No 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

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

2168D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1096.21	40.30	Eylea [BN]

■ RANIBIZUMAB

Note No 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 Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe

10374B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1042.60	40.30	^a Lucentis [NV]

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

10373Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1042.60	40.30	^a Lucentis [NV]

■ RANIBIZUMAB

Note Special Pricing Arrangements apply.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to pathologic myopia (PM), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to pathologic myopia (PM), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Grandfather treatment

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to pathologic myopia (PM), **AND**
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition for the same eye prior to 1 November 2018, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- The condition must not be due to pathologic myopia, **AND**
- The condition must not be due to age-related macular degeneration, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- The condition must not be due to pathologic myopia, **AND**
- The condition must not be due to age-related macular degeneration, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe

11480F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1042.60	40.30	^a Lucentis [NV]

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

11471R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1042.60	40.30	^a Lucentis [NV]

■ RANIBIZUMAB

Note No 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 Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.
- Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe

10138N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1042.60	40.30	^a Lucentis [NV]

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

1382R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1042.60	40.30	^a Lucentis [NV]

■ VERTEPORFIN

Note A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

Note The Department of Human Services should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

Authority required (STREAMLINED)

7583

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be predominantly classic (greater than or equal to 50%), **AND**
- The condition must be due to macular degeneration, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

verteporfin 15 mg injection, 1 vial

11307D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1935.91	40.30	Visudyne [NV]

■ VERTEPORFIN

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note The Department of Human Services should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

Note Written applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be predominantly classic (greater than or equal to 50%).

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a baseline visual acuity equal to or better than 6/60 (20/200).

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram.

Note No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

- The condition must be predominantly classic (greater than or equal to 50%), **AND**
- The condition must be due to macular degeneration, **AND**
- Patient must have been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form; and
 - a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form, which includes the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and
 - a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).
- A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram.

Note A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

verteporfin 15 mg injection, 1 vial

1349B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1935.91	40.30	Visudyne [NV]

OTHER OPHTHALMOLOGICALS
Other ophthalmologicals
■ CARBOMER-974P
Authority required (STREAMLINED)
6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

carbomer-974P 0.3% eye gel, 30 x 500 mg unit doses

5502N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*32.41	33.66	Poly Gel [AQ]

carbomer-974P 0.3% eye gel, 30 x 500 mg unit doses

8514D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*32.41	33.66	Poly Gel [AQ]

■ CARBOMER-980
Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carbomer-980 0.2% eye gel, 10 g

5503P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	5	..	14.30	15.55	^a Optifresh eye gel [PP]	^a PAA [UL]
			^B 3.85	18.15	15.55	^a Viscotears [UO]	

carbomer-980 0.2% eye gel, 10 g

8384G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	14.30	15.55	^a Optifresh eye gel [PP]	^a PAA [UL]
			^B 3.85	18.15	15.55	^a Viscotears [UO]	

■ CARBOMER-980
Authority required (STREAMLINED)
6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses

5504Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*37.27	38.52	Viscotears Gel PF [UO]

carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses

8578L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*37.27	38.52	Viscotears Gel PF [UO]

▪ **CARBOMER-980**

Note No applications for increased maximum quantities will be authorised.

Note No applications for repeats will be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

carbomer-980 0.2% eye gel, 10 g

9210R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	11	..	14.30	15.55	^a Optifresh eye gel [PP]	^a PAA [UL]
			^B 3.85	18.15	15.55	^a Viscotears [UO]	

▪ **CARMELLOSE SODIUM**

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carmellose sodium 0.5% eye drops, 15 mL

5507W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	14.43	15.68	Refresh Tears Plus [AG]

carmellose sodium 1% eye drops, 15 mL

5508X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	14.43	15.68	Refresh Liquigel [AG]

▪ **CARMELLOSE SODIUM**

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carmellose sodium 0.5% eye drops, 15 mL

8548X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	14.43	15.68	Refresh Tears Plus [AG]

carmellose sodium 1% eye drops, 15 mL

8593G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	14.43	15.68	Refresh Liquigel [AG]

▪ **CARMELLOSE SODIUM**

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

carmellose sodium 0.5% eye drops, 30 x 0.4 mL unit doses

2338C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*29.05	30.30	^a Optifresh Tears [PP]
			^B 6.21	*35.26	30.30	^a Cellufresh [AG]

carmellose sodium 0.5% eye drops, 30 x 0.4 mL unit doses

5506T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*29.05	30.30	^a Optifresh Tears [PP]
			^B 6.21	*35.26	30.30	^a Cellufresh [AG]

carmellose sodium 1% eye drops, 30 x 0.4 mL unit doses

2324H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*29.05	30.30	^a Optifresh Plus [PP]
			^B 6.21	*35.26	30.30	^a Celluvisc [AG]

carmellose sodium 1% eye drops, 30 x 0.4 mL unit doses

5505R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*29.05	30.30	^a Optifresh Plus [PP]
			^B 6.21	*35.26	30.30	^a Celluvisc [AG]

■ CARMELLOSE SODIUM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

carmellose sodium 0.5% eye drops, 15 mL

9211T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	11	..	14.43	15.68	Refresh Tears Plus [AG]

carmellose sodium 1% eye drops, 15 mL

9212W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	11	..	14.43	15.68	Refresh Liquigel [AG]

■ CARMELLOSE SODIUM + GLYCEROL

Note The in-use shelf life of Optive is 6 months from the date of opening.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

5556K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	14.43	15.68	Optive [AG]

OP

■ CARMELLOSE SODIUM + GLYCEROL

Note The in-use shelf life of Optive is 6 months from the date of opening.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

9355J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	14.43	15.68	Optive [AG]

NP

■ CARMELLOSE SODIUM + GLYCEROL

Note No 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 The in-use shelf life of Optive is 6 months from the date of opening.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

9356K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	7	..	14.43	15.68	Optive [AG]

■ DEXTRAN-70 + HYPROMELLOSE

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

1509K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	15.02	16.27	^a Poly-Tears [IQ]
			^b 4.00	19.02	16.27	^a Tears Naturale [AQ]

NP

■ DEXTRAN-70 + HYPROMELLOSE

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

5520M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	15.02	16.27	^a Poly-Tears [IQ]
			^b 4.00	19.02	16.27	^a Tears Naturale [AQ]

OP

■ DEXTRAN-70 + HYPROMELLOSE

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses

5521N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*36.37	37.62	Bion Tears [AQ]

dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses

8299T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*36.37	37.62	Bion Tears [AQ]

▪ **DEXTRAN-70 + HYPROMELLOSE**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

9216C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	11	..	15.02	16.27	^a Poly-Tears [IQ]
			^B 4.00	19.02	16.27	^a Tears Naturale [AQ]

▪ **HYALURONATE SODIUM**

Note The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.

Authority required (STREAMLINED)

4105

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

hyaluronate sodium 0.1% eye drops, 10 mL

2181T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	33.95	35.20	Hylo-Fresh [AE]

hyaluronate sodium 0.1% eye drops, 10 mL

2184Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	33.95	35.20	Hylo-Fresh [AE]

hyaluronate sodium 0.2% eye drops, 10 mL

2171G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	33.95	35.20	Hylo-Forte [AE]

hyaluronate sodium 0.2% eye drops, 10 mL

2253N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	33.95	35.20	Hylo-Forte [AE]

▪ **HYPROMELLOSE**

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

hypromellose 0.5% eye drops, 15 mL

2956N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	14.83	16.08	Methopt [QA]

hypromellose 0.3% w/w eye drops, 10 mL

11625W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	13.72	14.97	^a In a Wink Moisturising [IQ]
			^B 4.34	18.06	14.97	^a Genteal [AQ]

▪ **HYPROMELLOSE**

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

hypromellose 0.5% eye drops, 15 mL

5517J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	14.83	16.08	Methopt [QA]

hypromellose 0.3% w/w eye drops, 10 mL

11634H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	13.72	14.97	^a In a Wink Moisturising [IQ]
			^B 4.34	18.06	14.97	^a Genteal [AQ]

■ HYPROMELLOSE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

hypromellose 0.5% eye drops, 15 mL

9214Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.83	16.08	Methopt [QA]

hypromellose 0.3% w/w eye drops, 10 mL

11643T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	13.72	14.97	^a In a Wink Moisturising [IQ]
			^B 4.34	18.06	14.97	^a Genteal [AQ]

■ HYPROMELLOSE + CARBOMER-980
Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

5519L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	14.83	16.08	^a HPMC PAA [IQ]
			^B 4.80	19.63	16.08	^a Genteal gel [AQ]

■ HYPROMELLOSE + CARBOMER-980
Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

8564R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	14.83	16.08	^a HPMC PAA [IQ]
			^B 4.80	19.63	16.08	^a Genteal gel [AQ]

■ HYPROMELLOSE + CARBOMER-980

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

9215B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.83	16.08	^a HPMC PAA [IQ]
			^B 4.80	19.63	16.08	^a Genteal gel [AQ]

■ OCRIPLASMIN

Note Where authority approval for treatment for both eyes simultaneously is being sought, a maximum quantity of 2 vials may be requested.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Vitreomacular traction syndrome

Clinical criteria:

- Patient must have visual impairment due to vitreomacular traction (VMT) without a full thickness macular hole (FTMH);
OR

- Patient must have visual impairment due to vitreomacular traction (VMT) with a full thickness macular hole (FTMH) of a diameter of less than or equal to 400 micrometres, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 20/25 or worse in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography, **AND**
- The condition must have a vitreomacular adhesion diameter less than or equal to 1500 micrometres, **AND**
- Patient must not have an epiretinal membrane attached to the vitreomacular traction, **AND**
- The condition must be previously untreated in the eye proposed for treatment, **AND**
- Patient must not have received prior vitrectomy in the eye proposed for treatment, **AND**
- Patient must be symptomatic.

Treatment criteria:

- Must be treated by an ophthalmologist.

The prescriber must state which eye(s) is being treated at the time of application.

ocriplasmin 500 microgram/0.2 mL injection, 0.2 mL vial

10947E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4152.12	40.30	Jetrea [IJ]

▪ **PARAFFIN**

paraffin 1 g/g eye ointment, 2 x 3.5 g

1750D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	23.81	25.06	Poly Visc [IQ]
			^B 1.84	25.65	25.06	^a Ircal [PE]
						^a Refresh Night Time [AG]

paraffin 1 g/g eye ointment, 2 x 3.5 g

5522P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	23.81	25.06	Poly Visc [IQ]
			^B 1.84	25.65	25.06	^a Ircal [PE]
						^a Refresh Night Time [AG]

paraffin 1 g/g eye ointment, 3.5 g

1754H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*24.37	25.62	Poly Visc [IQ]

paraffin 1 g/g eye ointment, 3.5 g

5523Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	5	..	*24.37	25.62	Poly Visc [IQ]

▪ **PARAFFIN**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

paraffin 1 g/g eye ointment, 2 x 3.5 g

9218E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	23.81	25.06	Poly Visc [IQ]
			^B 1.84	25.65	25.06	^a Ircal [PE]
						^a Refresh Night Time [AG]

▪ **PARAFFIN**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

paraffin 1 g/g eye ointment, 3.5 g

9217D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	11	..	*24.37	25.62	Poly Visc [IQ]

▪ **PERFLUOROHXYLOCTANE**

Note The in-use shelf life of Novatears is 6 months from the date of opening.

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

perfluorohexyloctane 100% eye drops, 3 mL

11439C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	1	5	..	32.98	34.23	Novatears [AE]

perfluorohexyloctane 100% eye drops, 3 mL

11446K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	32.98	34.23	Novatears [AE]

■ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

5524R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	14.44	15.69	Systane [AQ]

■ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

8676P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	14.44	15.69	Systane [AQ]

■ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**Authority required (STREAMLINED)****6172**

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses

5532E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	5	..	*31.03	32.28	Systane [AQ]

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses

9170P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*31.03	32.28	Systane [AQ]

■ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

9219F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	11	..	14.44	15.69	Systane [AQ]

■ POLYVINYL ALCOHOL**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

polyvinyl alcohol 1.4% eye drops, 15 mL

2682E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	14.83	16.08	^a PVA Tears [PE]
			^b 1.39	16.22	16.08	^a Liquifilm Tears [AG]

■ POLYVINYL ALCOHOL**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

polyvinyl alcohol 1.4% eye drops, 15 mL

5526W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	14.83	16.08	^a PVA Tears [PE]
			^B 1.39	16.22	16.08	^a Liquifilm Tears [AG]

■ POLYVINYL ALCOHOL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

polyvinyl alcohol 1.4% eye drops, 15 mL

9220G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	14.83	16.08	^a PVA Tears [PE]
			^B 1.39	16.22	16.08	^a Liquifilm Tears [AG]

■ RETINOL PALMITATE + PARAFFIN

Note The in-use shelf life of VitA-POS is 6 months from the date of opening.

retinol palmitate 0.0138% + paraffin eye ointment, 5 g

2167C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	5	..	*24.37	25.62	VitA-POS [AE]

retinol palmitate 0.0138% + paraffin eye ointment, 5 g

2222Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*24.37	25.62	VitA-POS [AE]

■ RETINOL PALMITATE + PARAFFIN

Note The in-use shelf life of VitA-POS is 6 months from the date of opening.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

retinol palmitate 0.0138% + paraffin eye ointment, 5 g

2202X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	11	..	*24.37	25.62	VitA-POS [AE]

■ SOY LECITHIN + TOCOPHEROL + VITAMIN A

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% spray, 100 actuations

5545W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	5	..	*35.99	37.24	tearsagain [RB]

soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% spray, 100 actuations

9448G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*35.99	37.24	tearsagain [RB]

■ OTOLOGICALS

ANTIINFECTIVES

Antiinfectives

■ CIPROFLOXACIN

Authority required

Chronic suppurative otitis media

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person, **AND**
- Patient must be aged 1 month or older.

Authority required

Chronic suppurative otitis media

Population criteria:

- Patient must be less than 18 years of age.

Clinical criteria:

- Patient must have perforation of the tympanic membrane.

Authority required

Chronic suppurative otitis media

Population criteria:

- Patient must be less than 18 years of age.

Clinical criteria:

- Patient must have a grommet in situ.

ciprofloxacin 0.3% ear drops, 5 mL

2480M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	36.64	37.89	Ciloxan [NV]

CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION*Corticosteroids and antiinfectives in combination***■ FRAMYCETIN SULFATE + GRAMICIDIN + DEXAMETHASONE****framycetin sulfate 0.5% + gramicidin 0.005% + dexamethasone 0.05% ear drops, 8 mL**

2781J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	14.54	15.79	^a Otodex [AV]
			^B 2.41	16.95	15.79	^a Sofradex [SW]

■ TRIAMCINOLONE + NEOMYCIN + GRAMICIDIN + NYSTATIN**triamcinolone acetate 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 5 g**

2974M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	13.01	14.26	^a Otocomb Otic [FM]
			^B 1.70	14.71	14.26	^a Kenacomb Otic [QA]

triamcinolone acetate 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/mL ear drops, 7.5 mL

2971J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	15.54	16.79	^a Otocomb Otic [FM]
			^B 1.70	17.24	16.79	^a Kenacomb Otic [QA]

■ OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS**ANTIINFECTIVES***Antiinfectives***■ FRAMYCETIN SULFATE****framycetin sulfate 0.5% eye/ear drops, 8 mL**

1440T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	‡1	2	..	14.54	15.79	Soframycin [SW]

framycetin sulfate 0.5% eye/ear drops, 8 mL

5557L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	2	..	14.54	15.79	Soframycin [SW]

■ VARIOUS**■ ALLERGENS****ALLERGENS***Allergen extracts***■ HONEY BEE VENOM****honey bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack**

10621B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	290.49	40.30	Hymenoptera Honey Bee Venom [DE]

honey bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2886X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	227.25	40.30	Albey Bee Venom [DE]

■ PAPER WASP VENOM

Note Paper wasp venom is not European wasp venom

paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2918N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	227.25	40.30	Albey Paper Wasp Venom [DE]

paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack

10620Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	340.02	40.30	Hymenoptera Paper Wasp Venom [DE]

■ VESPUULA SPP VENOM**vespula spp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack**

10622C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	393.98	40.30	Hymenoptera Yellow Jacket Venom [DE]

vespula spp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2883R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	227.25	40.30	Albey Yellow Jacket Venom [DE]

■ ALL OTHER THERAPEUTIC PRODUCTS**ALL OTHER THERAPEUTIC PRODUCTS***Antidotes***■ NALOXONE****naloxone hydrochloride 1 mg/mL injection, 2 mL syringe**

11077B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	48.42	40.30	Prenoxad [FF]

naloxone hydrochloride 1 mg/mL injection, 2 mL syringe

11078C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	48.42	40.30	Prenoxad [FF]

naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10783M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	53.37	40.30	^a Naloxone Hydrochloride (DBL) [PF]	^a Naloxone Juno [JU]

naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10787R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	53.37	40.30	^a Naloxone Hydrochloride (DBL) [PF]	^a Naloxone Juno [JU]

*Drugs for treatment of hyperkalemia and hyperphosphatemia***■ LANTHANUM**

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.

Authority required (STREAMLINED)

5491

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 non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

lanthanum 500 mg chewable tablet, 2 x 45

9403X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	281.92	40.30	Fosrenol [ZI]

lanthanum 1 g chewable tablet, 6 x 15

9405B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	475.64	40.30	Fosrenol [ZI]

lanthanum 750 mg chewable tablet, 6 x 15

9404Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	423.07	40.30	Fosrenol [ZI]

SEVELAMER**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.

Authority required (STREAMLINED)**5491**

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 non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sevelamer hydrochloride 800 mg tablet, 180

2142R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	300.13	40.30	Renagel [GZ]

SUCROFERRIC OXYHYDROXIDE**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.

Authority required (STREAMLINED)**5491**

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 non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90

10250L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	424.42	40.30	Velphoro [VL]

Detoxifying agents for antineoplastic treatment**FOLINIC ACID****folinic acid 1 g/100 mL injection, 100 mL vial**

8969C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	50.17	40.30	Calcium Folate Ebewe [SZ]

folinic acid 300 mg/30 mL injection, 30 mL vial

9041W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	1	..	*56.75	40.30	^a Calcium Folate Ebewe [SZ]	^a Leucovorin Calcium (Hospira Pty Limited) [PF]

■ 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.

folinic acid 50 mg/5 mL injection, 5 mL vial

8740B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	2	..	*53.29	40.30	^a Leucovorin Calcium (Hospira Pty Limited) [PF]

folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules

1610R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	53.31	40.30	^a Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

■ FOLINIC ACID

Note For item codes 8812T and 1704Q, pharmaceutical benefits that have the form injection equivalent to 100 mg folinic acid in 10 mL are equivalent for the purposes of substitution.

folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules

1704Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	58.57	40.30	^a Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

folinic acid 100 mg/10 mL injection, 10 mL vial

8812T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*58.59	40.30	^a Calcium Folate Ebewe [SZ]

■ FOLINIC ACID**Restricted benefit**

Megaloblastic anaemias

Clinical criteria:

- The condition must be a result of folic acid deficiency from the use of folic acid antagonists.

folinic acid 15 mg tablet, 10

2308L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	93.20	40.30	Leucovorin Calcium (Hospira Pty Limited) [PF]

■ MESNA**Restricted benefit**

Urothelial toxicity

Treatment Phase: Prophylaxis or reduction of toxicity

Clinical criteria:

- The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

mesna 1 g/10 mL injection, 15 x 10 mL ampoules

8079F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	173.44	40.30	Uromitexan [BX]

mesna 400 mg/4 mL injection, 15 x 4 mL ampoules

8078E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	83.00	40.30	Uromitexan [BX]

Drugs for treatment of hypercalcemia**■ PHOSPHORUS****Authority required (STREAMLINED)**

5089

Hypophosphataemic rickets

Authority required (STREAMLINED)

5114

Vitamin D-resistant rickets

Authority required (STREAMLINED)

5095

Familial hypophosphataemia

Authority required (STREAMLINED)

5123

Hypercalcaemia

phosphorus 500 mg effervescent tablet, 100

2946C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	67.01	40.30	PHOSPHATE PHEBRA [FG]

*Other therapeutic products***■ POLYLACTIC ACID****Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).**Authority required**

Severe facial lipoatrophy

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-L-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

polylactic acid 150 mg injection, 1 vial

9475Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	4	..	*420.15	40.30	Sculptra [GA]

■ POLYLACTIC ACID**Note** No 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** Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.**Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).**Authority required**

Severe facial lipoatrophy

Treatment Phase: Maintenance PBS-subsidised treatment

Clinical criteria:

- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-L-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

polylactic acid 150 mg injection, 1 vial

9476R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*420.15	40.30	Sculptra [GA]

■ DIAGNOSTIC AGENTS**URINE TESTS****■ GLUCOSE AND KETONE INDICATOR URINE****Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

glucose and ketone indicator urine diagnostic strip, 50

3107M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*19.27	20.52	Keto-Diastix [DX]

■ GLUCOSE INDICATOR URINE**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

glucose indicator urine diagnostic strip, 50

3104J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*20.95	22.20	Diastix [DX]

GENERAL NUTRIENTS

OTHER NUTRIENTS

LONG CHAIN TRIGLYCERIDES

Note Carbzero is not nutritionally complete and is not intended for use as a sole source of nutrition.

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

Carbzero should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

long chain triglycerides oral liquid, 15 x 225 mL bottles

11438B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*208.47	40.30	Carbzero [VF]

MEDIUM CHAIN TRIGLYCERIDES

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6147

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

Authority required (STREAMLINED)

6191

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have chylous ascites; OR
- Patient must have chylothorax; OR
- Patient must have hyperlipoproteinaemia type 1; OR
- Patient must have long chain fatty acid oxidation disorders; OR
- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

medium chain triglycerides oral liquid, 15 x 225 mL bottles

11444H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*268.99	40.30	Betaquik [VF]

MEDIUM CHAIN TRIGLYCERIDES

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6181

Chylous ascites

Authority required (STREAMLINED)

6134

Chylothorax

Authority required (STREAMLINED)

6164

Fat malabsorption

Clinical criteria:

- The condition must be due to liver disease; OR
- The condition must be due to short gut syndrome; OR
- The condition must be due to cystic fibrosis; OR
- The condition must be due to gastrointestinal disorders.

Authority required (STREAMLINED)

6203

Hyperlipoproteinaemia type 1

Authority required (STREAMLINED)

6155

Intractable childhood epilepsy

Clinical criteria:

- Patient must require a ketogenic diet.

Authority required (STREAMLINED)

6135

Cerebrospinal fluid glucose transporter defect

Clinical criteria:

- Patient must require a ketogenic diet.

Authority required (STREAMLINED)

6146

Long chain fatty acid oxidation disorders

medium chain triglycerides oral liquid, 250 mL bottle

9327X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*165.87	40.30	Liquigen [SB]

medium chain triglycerides oral oil, 500 mL

3128P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*45.17	40.30	MCT Oil [SB]

■ **PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS AND MINERALS**

Note No increase in the maximum number of repeats may be authorised.

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

Population criteria:

- Patient must be aged from 1 to 10 years inclusive.

protein formula with carbohydrate, fat, vitamins and minerals oral liquid, 8 x 500 mL pouches

11110R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*1502.99	40.30	Nutrini Peptisorb Energy [NU]

Fat/carbohydrates/proteins/minerals/vitamins, combinations

■ **AMINO ACID SYNTHETIC FORMULA**

Note Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid synthetic formula powder for oral liquid, 400 g

1521C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*429.79	40.30	Neocate Junior Vanilla [SB]

amino acid synthetic formula powder for oral liquid, 400 g

2250K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*429.79	40.30	EleCare [AB]

■ AMINO ACID SYNTHETIC FORMULA

Note No 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

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid synthetic formula powder for oral liquid, 400 g

1180D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*288.27	40.30	Neocate Junior Vanilla [SB]

amino acid synthetic formula powder for oral liquid, 400 g

8574G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*288.27	40.30	EleCare [AB]

■ AMINO ACID SYNTHETIC FORMULA

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.
- Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

amino acid synthetic formula powder for oral liquid, 400 g

1192R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*288.27	40.30	Neocate Junior Vanilla [SB]

amino acid synthetic formula powder for oral liquid, 400 g

8575H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*288.27	40.30	EleCare [AB]

■ **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**

Note No 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

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g

2246F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	5	..	*309.15	40.30	Neocate LCP [SB]

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g

9339M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	5	..	*309.15	40.30	EleCare LCP [AB]

■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.
- Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g

2560R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*309.15	40.30	Neocate LCP [SB]

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g

9340N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*309.15	40.30	EleCare LCP [AB]

■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

1545H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*511.63	40.30	Neocate Gold [SB]

■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note No 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

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

5466Q

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*342.83	40.30	Neocate Gold [SB]

NP

AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

5467R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	5	..	*342.83	40.30	Neocate Gold [SB]

■ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal

antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

2900P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*342.83	40.30	Alfamino [NT]

■ **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- (i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

2928D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*342.83	40.30	Alfamino [NT]

■ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required (STREAMLINED)****6174**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

- Patient must be up to the age of 24 months.

Authority required (STREAMLINED)**6193**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

Population criteria:

- Patient must be up to the age of 24 months.

Authority required (STREAMLINED)**6204**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)**6137**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Population criteria:

- Patient must be up to the age of 24 months.
- The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)**6182**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Population criteria:

- Patient must be up to the age of 24 months.
- The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)**6194**

Biliary atresia

Authority required (STREAMLINED)**6157**

Chronic liver failure with fat malabsorption

Authority required (STREAMLINED)**6205**

Chylous ascites

Authority required (STREAMLINED)**6195**

Cystic fibrosis

Authority required (STREAMLINED)**6158**

Enterokinase deficiency

Authority required (STREAMLINED)**6166**

Proven fat malabsorption

Authority required (STREAMLINED)**6148**

Severe diarrhoea of greater than 2 weeks duration

Population criteria:

- Patient must be aged less than 4 months.

Authority required (STREAMLINED)**6138**

Severe intestinal malabsorption including short bowel syndrome

protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 450 g

8259Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	5	..	*87.79	40.30	Aptamil Gold+ Pepti-Junior [NU]

■ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required (STREAMLINED)****6174**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

- Patient must be up to the age of 24 months.

Authority required (STREAMLINED)**6193**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

Population criteria:

- Patient must be up to the age of 24 months.

Authority required (STREAMLINED)**6204**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)**6137**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)**6182**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)**6194**

Biliary atresia

Authority required (STREAMLINED)**6157**

Chronic liver failure with fat malabsorption

Authority required (STREAMLINED)**6205**

Chylous ascites

Authority required (STREAMLINED)**6195**

Cystic fibrosis

Authority required (STREAMLINED)**6158**

Enterokinase deficiency

Authority required (STREAMLINED)**6166**

Proven fat malabsorption

Authority required (STREAMLINED)**6148**

Severe diarrhoea of greater than 2 weeks duration

Population criteria:

- Patient must be aged less than 4 months.

Authority required (STREAMLINED)**6138**

Severe intestinal malabsorption including short bowel syndrome

Authority required (STREAMLINED)**6206**

Chylothorax

protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 400 g

2676W

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*133.71	40.30	Alfaré [NT]

■ TRIGLYCERIDES MEDIUM CHAIN FORMULA**Note** No increase in the maximum number of repeats may be authorised.**Note** No increase in the maximum quantity or number of units may be authorised.**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

triglycerides medium chain formula oral liquid, 8 x 500 mL pouches

10375C

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*706.03	40.30	Nutrini Peptisorb [SB]

triglycerides medium chain formula powder for oral liquid, 400 g

10152H

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*395.39	40.30	Monogen [SB]

triglycerides medium chain formula powder for oral liquid, 400 g

10155L

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*356.91	40.30	Lipistart [VF]

■ TRIGLYCERIDES MEDIUM CHAIN FORMULA**Note** No increase in the maximum number of repeats may be authorised.**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.**Restricted benefit**

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

triglycerides medium chain formula powder for oral liquid, 400 g

10154K

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*330.59	40.30	Peptamen Junior [NT]

■ TRIGLYCERIDES MEDIUM CHAIN FORMULA**Note** No increase in the maximum number of repeats may be authorised.**Note** No increase in the maximum quantity or number of units may be authorised.**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.**Restricted benefit**

Hyperlipoproteinaemia type 1

Restricted benefit

Long chain fatty acid oxidation disorders

Restricted benefit

Chylous ascites

Restricted benefit

Chylothorax

triglycerides medium chain formula powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1938B	8	5	..	*356.91	40.30	Lipistart [VF]

triglycerides medium chain formula powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8478F	8	5	..	*395.39	40.30	Monogen [SB]

Carbohydrates**■ MODIFIED LONG CHAIN AMYLOPECTIN****Restricted benefit**

Glycogen storage disease

modified long chain amylopectin powder for oral liquid, 30 x 60 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9386B	4	5	..	*639.83	40.30	Glycosade [VF]

Amino acids/carbohydrates/minerals/vitamins, combinations**■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES****Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g

10522T

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*353.71	40.30	Alfamino Junior [NT]

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g

11161K

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*353.71	40.30	Neocate Junior [SB]

■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.
- Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

- Patient must be 18 years of age or less.
- Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g

10527C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*353.71	40.30	Alfamino Junior [NT]

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g

11183N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*353.71	40.30	Neocate Junior [SB]

Milk substitutes

▪ MILK POWDER LACTOSE INTOLERANCE FORMULA

Note No 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 No more than 1 application per patient will be authorised.

Authority required

Acute lactose intolerance

Population criteria:

- Patient must be up to the age of 12 months.
- The date of birth of the patient must be provided at the time of application.

milk powder lactose intolerance formula powder for oral liquid, 900 g

11209Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	..	..	*90.09	40.30	S-26 Original Alula L.I. [AS]

▪ **MILK POWDER SYNTHETIC LOW CALCIUM**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Hypercalcaemia

Population criteria:

- Patient must be under the age of 4 years.

milk powder synthetic low calcium powder for oral liquid, 400 g

3092R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*356.27	40.30	Locasol [SB]

Other combinations of nutrients

▪ **AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS**

Note Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

- Patient must be 18 years of age or less.
- Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Clinical criteria:

- Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

- Patient must be 18 years of age or less.
- Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g

11343B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*491.95	40.30	Neocate Syneo [SB]

▪ **AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS**

Note No 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

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g

11331J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	5	..	*329.71	40.30	Neocate Syneo [SB]

NP

■ AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk anaphylaxis

Treatment criteria:

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:

- The condition must not be isolated infant colic or reflux.

Population criteria:

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

- Patient must have failed to respond to protein hydrolysate formulae; OR
- Patient must have been receiving parenteral nutrition.

Note A risk/benefit analysis prior to treatment, and continuous patient monitoring from a health care professional is required for the use of this product, for this indication.

amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g

11340W



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*329.71	40.30	Neocate Syneo [SB]

AMINO ACID FORMULA WITH CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE

Restricted benefit

Phenylketonuria

amino acid formula with carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for, 30 x 20 g sachets

10806R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1000.79	40.30	PKU Go [OH]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE**

Restricted benefit

Phenylketonuria

amino acid formula with fat, carbohydrate without phenylalanine tablet: modified release, 4 x 110 g

10683G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	7	5	..	*1930.01	40.30	PKU Easy Microtabs [OH]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

Note The level of iron in this product is below the recommended daily intake (RDI) for infants and should be supplemented by other sources where appropriate.

Restricted benefit

Phenylketonuria

amino acid formula with fat, carbohydrate, vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine and supplemented with docosahexaenoic acid oral liquid, 20 x 500 mL bottles

10822N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*634.15	40.30	PKU Baby [OH]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

Restricted benefit

Pyridoxine non-responsive homocystinuria

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL bottles

3417W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2395.67	40.30	HCU Anamix junior LQ [SB]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE**

Restricted benefit

Phenylketonuria

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for, 30 x 34 g bottles

10632N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*1906.24	40.30	PKU Easy Shake & Go [OH]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE**

Restricted benefit

Tyrosinaemia

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine oral liquid: powder for, 30 x 34 g bottles

10934L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2956.55	40.30	TYR Easy Shake & Go [OH]

■ **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

Restricted benefit

Tyrosinaemia

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans

9330C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2395.67	40.30	TYR Anamix junior LQ [SB]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

Restricted benefit

Proven glutaric aciduria type 1

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 18 g sachets

10715Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*1819.07	40.30	GA1 Anamix Junior [NU]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

Restricted benefit

Proven glutaric aciduria type 1

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 500 g

10466W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	9	5	..	*2659.69	40.30	XLYS, LOW TRY Maxamum [SB]

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 400 g

2650L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*654.35	40.30	GA1 Anamix infant [SB]

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 24 g sachets

9438R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1819.11	40.30	GA gel [VF]

amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 25 g sachets

5484P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2724.03	40.30	GA express 15 [VF]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Restricted benefit

Pyridoxine non-responsive homocystinuria

amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets

2639X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1732.07	40.30	HCU cooler 10 [VF]

amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 125 mL pouches

1548L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*2549.86	40.30	HCU Lophlex LQ 20 [SB]

amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 24 g sachets

8677Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1732.07	40.30	HCU gel [VF]

amino acid formula with vitamins and minerals without methionine powder for oral liquid, 500 g

8416Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*2230.19	40.30	XMET Maxamum [SB]

amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets

2640Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*3349.15	40.30	HCU cooler 20 [VF]

amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 25 g sachets

8744F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2549.91	40.30	HCU express 15 [VF]

amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL pouches

9133Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2549.91	40.30	HCU cooler 15 [VF]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Restricted benefit

Pyridoxine non-responsive homocystinuria

amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 36 g sachets

10693T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1732.07	40.30	HCU Anamix Junior [NU]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Restricted benefit

Pyridoxine non-responsive homocystinuria

Population criteria:

- Patient must be an infant or a very young child.

amino acid formula with vitamins and minerals without methionine powder for oral liquid, 400 g

8417B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*621.87	40.30	HCU Anamix infant [SB]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE

Restricted benefit

Methylmalonic acidemia

Restricted benefit

Propionic acidemia

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 24 g sachets

3444G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1732.07	40.30	MMA/PA gel [VF]

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 400 g

8058D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*621.87	40.30	MMA/PA Anamix infant [SB]

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 25 g sachets

3443F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2549.91	40.30	MMA/PA express 15 [VF]

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 500 g

8061G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*2230.19	40.30	XMTVI Maxamum [SB]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE

Restricted benefit

Methylmalonic acidemia

Restricted benefit

Propionic acidemia

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 18 g sachets

10730R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*1731.95	40.30	MMA/PA Anamix Junior [NU]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

Restricted benefit

Phenylketonuria

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL cans

2474F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1681.31	40.30	PKU Cooler 20 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets

5483N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*856.43	40.30	PKU squeeze [VF]

amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 25 g sachets

8591E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1265.83	40.30	PKU express 15 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL pouch

10410X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1265.15	40.30	PKU Air 15 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL cans

2382J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*836.39	40.30	PKU Cooler 10 [VF]

amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 27.8 g sachets

8804J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1662.27	40.30	PKU Lophlex [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL cans

9396M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1040.03	40.30	PKU Anamix Junior LQ [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouch

10411Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1681.31	40.30	PKU Air 20 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL cans

9021T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1662.27	40.30	PKU Lophlex LQ 20 [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL

8746H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*1075.14	40.30	Easiphen [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL cans

8846N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1265.15	40.30	PKU Cooler 15 [VF]

amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g

2739E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*1106.83	40.30	XP Maxamum [SB]

amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 24 g sachets

8555G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*856.43	40.30	PKU gel [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL cans

9397N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*857.09	40.30	PKU Lophlex LQ 10 [SB]

AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 34 g, 30, 1

1909L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1681.31	40.30	PKU express 20 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g jars

2806Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*1512.10	40.30	PKU Lophlex Sensation 20 [SB]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

Note Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

Restricted benefit

Phenylketonuria

amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 36 g sachets

10258X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*857.47	40.30	PKU Anamix Junior [SB]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

Restricted benefit

Tyrosinaemia

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2674R	4	5	..	*1732.07	40.30	TYR cooler 10 [VF]

NP

amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 34 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11151X	4	5	..	*3349.15	40.30	TYR express 20 [VF]

NP

amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 25 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8667E	4	5	..	*2549.91	40.30	TYR express 15 [VF]

NP

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL cans

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9132P	4	5	..	*2549.91	40.30	TYR cooler 15 [VF]

NP

amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8445L	8	5	..	*621.87	40.30	TYR Anamix infant [SB]

NP

amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 500 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3078B	8	5	..	*2230.19	40.30	XPhen, Tyr Maxamum [SB]

NP

AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid 125 mL, 30, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1547K	3	5	..	*2549.86	40.30	TYR Lophlex LQ 20 [SB]

NP

amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 24 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8631G	4	5	..	*1732.07	40.30	TYR gel [VF]

NP

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2701E	4	5	..	*3349.15	40.30	TYR cooler 20 [VF]

NP

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

Note Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

Restricted benefit

Tyrosinaemia

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 36 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10260B	4	5	..	*1732.07	40.30	TYR Anamix Junior [SB]

NP

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Restricted benefit

Maple syrup urine disease

amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 24 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8592F	4	5	..	*1732.07	40.30	MSUD gel [VF]

NP

amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 500 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8057C	8	5	..	*2230.19	40.30	MSUD Maxamum [SB]

NP

amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 500 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8310J	4	5	..	*2203.55	40.30	MSUD AID III [SB]

NP

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 125 mL pouches

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1546J	3	5	..	*2549.86	40.30	MSUD Lophlex LQ 20 [SB]

NP

amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 25 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8632H	4	5	..	*2549.91	40.30	MSUD express 15 [VF]

NP

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2651M	4	5	..	*1732.07	40.30	MSUD cooler 10 [VF]

NP

amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 400 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2380G	8	5	..	*621.87	40.30	MSUD Anamix infant [SB]

NP

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL pouches

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2375B	4	5	..	*2549.91	40.30	MSUD cooler 15 [VF]

NP

amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 34 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1914R	4	5	..	*3358.71	40.30	MSUD express 20 [VF]

NP

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2654Q	4	5	..	*3349.15	40.30	MSUD cooler 20 [VF]

NP

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Note Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

Restricted benefit

Maple syrup urine disease

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 36 g sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10259Y	4	5	..	*1732.07	40.30	MSUD Anamix Junior [SB]

NP

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**Restricted benefit**

Maple syrup urine disease

amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL bottles

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
9499Y	4	5	..	*2395.67	40.30	MSUD Anamix Junior LQ [SB]

NP

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID

Restricted benefit

Phenylketonuria

amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 12.5 g sachets

11185Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*1000.75	40.30	PKU Anamix First Spoon [SB]

■ AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE

Restricted benefit

Phenylketonuria

amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine powder for oral liquid, 400 g

8479G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*568.75	40.30	PKU Anamix infant [SB]

■ AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE

Note The level of iron in this product is below the recommended daily intake (RDI) for infants and should be supplemented by other sources where appropriate.

Restricted benefit

Phenylketonuria

amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine powder for oral liquid, 400 g

11653H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*604.67	40.30	PKU Start [VF]

■ AMINO ACID FORMULA WITHOUT PHENYLALANINE

Restricted benefit

Phenylketonuria

amino acid formula without phenylalanine 1 g tablet, 75

8678R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	24	5	..	*1166.83	40.30	Phlexy-10 [SB]

■ AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Restricted benefit

Maple syrup urine disease

amino acid formula without valine, leucine and isoleucine containing 5 g of protein equivalent oral liquid: powder for, 30 x 6 g sachets

10161T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*3104.11	40.30	MSUD amino5 [VF]

■ ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

Restricted benefit

Peroxisomal biogenesis disorders

arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets

10036F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*345.75	40.30	keyomega [VF]

■ ARGININE WITH CARBOHYDRATE

Note Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

Restricted benefit

Urea cycle disorders

arginine with carbohydrate containing 5 g arginine oral liquid: powder for, 30 x 7.6 g sachets

10093F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*966.39	40.30	Arginine 5000 [VF]

arginine with carbohydrate containing 500 mg arginine oral liquid: powder for, 30 x 4 g sachets

9437Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	4	5	..	*486.95	40.30	Arginine 500 [VF]

arginine with carbohydrate containing 2 g arginine oral liquid: powder for, 30 x 4 g sachets

5482M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	4	5	..	*727.91	40.30	Arginine 2000 [VF]

■ CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS**Restricted benefit**

Proven inborn errors of protein metabolism

Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

carbohydrate, fat, vitamins, minerals and trace elements powder for oral liquid, 400 g

8369L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	8	5	..	*252.19	40.30	Energivit [SB]

■ CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID**Restricted benefit**

Proven inborn errors of protein metabolism

Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosaheptaenoic acid providing 200 kilocalories powder for oral liquid, 30 x 43 g sachets

10039J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	4	5	..	*445.43	40.30	basecal 200 [VF]

■ CITRULLINE**Note** Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism**Restricted benefit**

Urea cycle disorders

Clinical criteria:

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

citrulline 1 g tablet, 300

10736C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	±1	5	..	1197.79	40.30	Citrulline Easy [OH]

■ CITRULLINE WITH CARBOHYDRATE**Note** Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.**Restricted benefit**

Urea cycle disorders

Clinical criteria:

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

citrulline with carbohydrate containing 1 g citrulline powder for oral liquid, 30 x 4 g sachets

5481L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	4	5	..	*486.95	40.30	Citrulline 1000 [VF]

■ DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE**Restricted benefit**

Peroxisomal biogenesis disorders

docosaheptaenoic acid with carbohydrate containing 200 mg docosaheptaenoic acid oral liquid: powder for, 30 x 4g sachets

10040K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	4	5	..	*345.75	40.30	docomega [VF]

■ ESSENTIAL AMINO ACIDS FORMULA**Restricted benefit**

Gyrate atrophy of the choroid and retina

Restricted benefit

Urea cycle disorders

essential amino acids formula powder for oral liquid, 2 x 200 g

9329B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*1137.73	40.30	Essential Amino Acid Mix [SB]

■ ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C**Restricted benefit**

Gyrate atrophy of the choroid and retina

Restricted benefit

Urea cycle disorders

essential amino acids formula with minerals and vitamin C powder for oral liquid, 400 g

2027Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*512.64	40.30	Dialamine [SB]

■ ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS**Restricted benefit**

Gyrate atrophy of the choroid and retina

Restricted benefit

Urea cycle disorders

essential amino acids formula with vitamins and minerals powder for oral liquid, 50 x 12.5 g sachets

9385Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1300.59	40.30	EAA Supplement [VF]

■ GLYCINE WITH CARBOHYDRATE**Restricted benefit**

Isovaleric acidemia

glycine with carbohydrate containing 500 mg glycine powder for oral liquid, 30 x 4 g sachets

10195N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*512.35	40.30	Glycine500 [VF]

■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS**Restricted benefit**

Tyrosinaemia

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent bar, 14 x 81 g

11290F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*2907.31	40.30	Tylactin Complete [QH]

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons

10528D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*3104.15	40.30	Tylactin RTD [QH]

■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS**Restricted benefit**

Phenylketonuria

glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 60 x 20 g sachets

11084J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*1312.24	40.30	PKU Restore [QH]

glycomacropeptide and essential amino acids with vitamins and minerals containing 20 g of protein equivalent powder for oral liquid, 30 x 32 g sachets

11279P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2068.79	40.30	PKU Build 20 [QH]

glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent powder for oral liquid, 60 x 16 g sachets

11287C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1073.17	40.30	PKU Build 10 [QH]

glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g

2644E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	14	5	..	*1289.09	40.30	Camino Pro Complete [QH]

glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 49 g sachets

10652P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1571.03	40.30	Camino Pro Bettermilk [QH]

glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 51 g sachets

10992M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2068.79	40.30	PKU Bettermilk Lite [QH]

■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Note This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

Restricted benefit

Phenylketonuria

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g protein oral liquid, 30 x 250 mL cartons

10332T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1570.95	40.30	PKU Glytactin RTD 15 [QH]

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons

11640P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1570.95	40.30	PKU Glytactin RTD 15 Lite [QH]

■ GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE**Restricted benefit**

Phenylketonuria

glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 27 g sachets

11245W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1571.03	40.30	PKU Sphere15 [VF]

glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 35 g sachets

11071Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2068.79	40.30	PKU Sphere20 [VF]

■ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

Keyo should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 48 x 100 g tubs

11108P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*866.44	40.30	Keyo [VF]

■ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR

- Patient must have a glucose transport protein defect; OR
 - Patient must have pyruvate dehydrogenase deficiency.
- KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid, 32 x 200 mL cartons

10185C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	5	..	*932.24	40.30	KetoCal 4:1 LQ [SB]

■ **HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**

Note Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
 - Patient must have a glucose transport protein defect; OR
 - Patient must have pyruvate dehydrogenase deficiency.
- KetoCal 3:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) powder for oral liquid, 300 g

2652N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	24	5	..	*979.87	40.30	KetoCal 3:1 [SB]

■ **HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**

Note Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
 - Patient must have a glucose transport protein defect; OR
 - Patient must have pyruvate dehydrogenase deficiency.
- KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) powder for oral liquid, 300 g

9446E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	24	5	..	*979.87	40.30	KetoCal 4:1 [SB]

■ **ISOLEUCINE WITH CARBOHYDRATE**

Restricted benefit

Maple syrup urine disease

isoleucine with carbohydrate containing 50 mg isoleucine oral liquid: powder for, 30 x 4 g sachets

9134R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*438.79	40.30	Isoleucine 50 [VF]

isoleucine with carbohydrate containing 1 g isoleucine oral liquid: powder for, 30 x 4 g sachets

9436P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*482.15	40.30	Isoleucine 1000 [VF]

■ **MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE**

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

milk protein and fat formula with vitamins and minerals carbohydrate free powder for oral liquid, 225 g

8630F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	24	5	..	*524.11	40.30	Carbohydrate Free Mixture [SB]

■ PHENYLALANINE WITH CARBOHYDRATE

Restricted benefit

Tyrosinaemia

phenylalanine with carbohydrate containing 50 mg phenylalanine oral liquid: powder for, 30 x 4 g sachets

9384X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	4	5	..	*438.79	40.30	Phenylalanine 50 [VF]

■ PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

Restricted benefit

Phenylketonuria

protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid oral liquid, 30 x 130 mL pouches

10658Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	5	5	..	*1905.19	40.30	PKU Easy [OH]

■ SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 384 mL can

8577K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	120	5	..	*541.39	40.30	RCF [AB]

■ TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER

Restricted benefit

Proven inborn errors of protein metabolism

Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cartons

9308X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	6	5	..	*315.25	40.30	ProZero [VF]

triglycerides long chain with glucose polymer oral liquid, 6 x 1 L cartons

9309Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	4	5	..	*280.07	40.30	ProZero [VF]

triglycerides long chain with glucose polymer oral liquid, 27 x 200 mL cartons

10189G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	2	5	..	*171.63	40.30	Sno-Pro [SB]

■ TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER

Restricted benefit

Proven inborn errors of protein metabolism

Clinical criteria:

- Patient must be unable to meet their energy requirements with permitted food and formulae.

triglycerides medium chain and long chain with glucose polymer powder for oral liquid, 400 g

3136C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
(NP)	8	5	..	*233.15	40.30	Duocal [SB]

■ TRIGLYCERIDES MEDIUM CHAIN FORMULA

Note No 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 Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Authority required (STREAMLINED)

6165

Chylous ascites

Authority required (STREAMLINED)

6192

Chylothorax

Authority required (STREAMLINED)**6173**

Fat malabsorption

Clinical criteria:

- The condition must be due to liver disease; OR
- The condition must be due to short gut syndrome; OR
- The condition must be due to cystic fibrosis; OR
- The condition must be due to gastrointestinal disorders.

Authority required (STREAMLINED)**6156**

Hyperlipoproteinaemia type 1

Authority required (STREAMLINED)**6136**

Long chain fatty acid oxidation disorders

triglycerides medium chain formula powder for oral liquid, 30 x 16 g sachets

9383W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*197.91	40.30	MCT Pro-Cal [VF]

■ TYROSINE WITH CARBOHYDRATE**Restricted benefit**

Phenylketonuria

tyrosine with carbohydrate containing 1 g tyrosine oral liquid: powder for, 30 x 4 g sachets

9165J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*438.79	40.30	Tyrosine 1000 [VF]

■ VALINE WITH CARBOHYDRATE**Restricted benefit**

Maple syrup urine disease

valine with carbohydrate containing 1 g valine oral liquid: powder for, 30 x 4 g sachets

9434M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*482.15	40.30	Valine 1000 [VF]

valine with carbohydrate containing 50 mg valine oral liquid: powder for, 30 x 4 g sachets

9135T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*438.79	40.30	Valine 50 [VF]

■ VITAMINS, MINERALS AND TRACE ELEMENTS**Note** Phlexy-Vits must only be used under strict supervision of a dietician and a paediatrician.**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

Clinical criteria:

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

Population criteria:

- Patient must be aged 3 years or older.

vitamins, minerals and trace elements powder for oral liquid, 30 x 7 g sachets

11200L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	275.08	40.30	Phlexy-Vits [SB]

■ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE**Note** FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

Clinical criteria:

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

Population criteria:

- Patient must be aged 3 years or older.

vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 30 x 6 g sachets

10149E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	275.08	40.30	FruitiVits [VF]

■ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

Note Paediatric Seravit must only be used under strict supervision of a dietitian and a paediatrician.

Restricted benefit

Dietary management of conditions requiring a highly restrictive therapeutic diet

Clinical criteria:

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

Population criteria:

- Patient must be an infant or a child.

vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 200 g

9328Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*364.99	40.30	Paediatric Seravit [SB]

■ WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**Authority required (STREAMLINED)**

6190

Chronic renal failure

Population criteria:

- Patient must be an infant or a young child.

Clinical criteria:

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose powder for oral liquid, 10 x 100 g sachets

9382T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	9	5	..	*1274.32	40.30	RenaStart [VF]

whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose powder for oral liquid, 6 x 400 g cans

2870C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1358.27	40.30	Renastart [VF]

■ WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**Authority required (STREAMLINED)**

6190

Chronic renal failure

Population criteria:

- Patient must be an infant or a young child.

Clinical criteria:

- Patient must require treatment with a low protein and a low phosphorus diet; OR
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose powder for oral liquid, 400 g

8587Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	16	5	..	*862.75	40.30	Kindergen [SB]

Palliative Care

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ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

STOMATOLOGICAL PREPARATIONS

Other agents for local oral treatment

BENZYDAMINE

Authority required (STREAMLINED)

6197

Painful mouth

Clinical criteria:

- Patient must be receiving palliative care.

benzydamine hydrochloride 0.15% mouthwash, 500 mL

5385K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	3	..	22.67	23.92	Diffiam [IL]

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, semisynthetic, quaternary ammonium compounds

HYOSCINE BUTYLBROMIDE

Authority required (STREAMLINED)

6207

For use in patients receiving palliative care

hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

5317W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	6	3	..	*85.51	40.30	^a Buscopan [VZ]	^a HYOSCINE BUTYLBROMIDE SXP [XC]

PROPULSIVES

Propulsives

METOCLOPRAMIDE

Authority required (STREAMLINED)

6084

Nausea or gastric stasis

Clinical criteria:

- Patient must be receiving palliative care.

metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules

10762K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	..	..	*34.31	35.56	Maxolon [IL]

DRUGS FOR CONSTIPATION

DRUGS FOR CONSTIPATION

Contact laxatives

BISACODYL

Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

bisacodyl 10 mg suppository, 12

5304E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*21.82	23.07	Petrus Bisacodyl Suppositories [PP]

bisacodyl 10 mg suppository, 10

5303D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*24.10	25.35	^a Petrus Bisacodyl Suppositories [PP]
			^B 1.29	*25.39	25.35	^a Dulcolax [VZ]

bisacodyl 5 mg enteric tablet, 200

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5301B	1	3	..	17.47	18.72	Lax-Tab [AE]

NP

*Bulk-forming laxatives***■ RHAMNUS FRANGULA + STERCULIA**Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5322D	±1	3	..	25.58	26.83	Normacol Plus [NE]

NP

*Osmotically acting laxatives***■ MACROGOL-3350**Authority required (STREAMLINED)**6170**

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

macrogol-3350 1 g/g powder for oral liquid, 510 g

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5426N	2	3	..	*26.63	27.88	OsmoLax [KY]

NP

■ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDEAuthority required (STREAMLINED)**6171**

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

macrogol-3350 13.125 g/25 mL + sodium chloride 350.7 mg/25 mL + sodium bicarbonate 178.5 mg/25 mL + potassium chloride 46.6 mg/25 mL oral liquid, 500 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10127B	2	3	..	*21.57	22.82	Movicol Liquid [NE]

NP

macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
5389P	2	3	..	*26.63	27.88	^a APO-MACROGOL plus ELECTROLYTES [TX] ^a LaxaCon [EA] ^a Macrovic [RF] ^a Movicol [NE]	^a Chemists' Own Macrogol with Electrolytes [RW] ^a lax-sachets [AE] ^a Molaxole [GO]

NP

*Enemas***■ BISACODYL**Restricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

bisacodyl 10 mg/5 mL enema, 25 x 5 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5302C	±1	3	..	38.89	40.14	Bisalax [AS]

NP

■ CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOLRestricted benefit

Constipation

Clinical criteria:

- Patient must be receiving palliative care.

MUSCULO-SKELETAL SYSTEM

sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL

5331N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*29.75	31.00	Micolette [AE]

Peripheral opioid receptor antagonists

■ METHYLNALTREXONE

Authority required (STREAMLINED)

6180

Opioid-induced constipation

Clinical criteria:

- The treatment must be in combination with oral laxatives, **AND**
- Patient must be receiving palliative care, **AND**
- Patient must have failed to respond to laxatives.

methylnaltrexone bromide 12 mg/0.6 mL injection, 7 x 0.6 mL vials

5424L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	264.19	40.30	Relistor [LM]

methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial

5423K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	7	..	..	*264.22	40.30	Relistor [LM]

■ MUSCULO-SKELETAL SYSTEM

■ ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS

Acetic acid derivatives and related substances

■ DICLOFENAC

Restricted benefit

Severe pain

Clinical criteria:

- Patient must be receiving palliative care.

diclofenac sodium 50 mg enteric tablet, 50

5362F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	13.53	14.78	^a APO-Diclofenac [TX] ^a Diclofenac Amneal [ED] ^a Diclofenac Sandoz [SZ] ^a Pharmacor Diclofenac 50 [CR]	^a Clonac 50 [RW] ^a Diclofenac AN [EA] ^a Fenac [AF]
			^B 3.46	16.99	14.78	^a Voltaren 50 [NV]	

diclofenac sodium 25 mg enteric tablet, 50

5361E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*14.43	15.68	^a APO-Diclofenac [TX] ^a Diclofenac Amneal [ED] ^a Diclofenac Sandoz [SZ]	^a Clonac 25 [RW] ^a Diclofenac AN [EA] ^a Fenac 25 [AF]
			^B 3.44	*17.87	15.68	^a Voltaren 25 [NV]	

diclofenac sodium 100 mg suppository, 20

5363G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*27.91	29.16	Voltaren 100 [NV]

■ INDOMETACIN

Restricted benefit

Severe pain

Clinical criteria:

- Patient must be receiving palliative care.

indometacin 25 mg capsule, 50

5377B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*17.09	18.34	^a Arthrexin [AF]
			^B 4.04	*21.13	18.34	^a Indocid [AS]

indometacin 100 mg suppository, 20

5378C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*25.47	26.72	Indocid [AS]

Propionic acid derivatives

■ IBUPROFEN

Restricted benefit

Severe pain

Clinical criteria:

- Patient must be receiving palliative care.

ibuprofen 400 mg tablet, 30

5368M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*17.23	18.48	^a APO-Ibuprofen 400 [TX]
			^B 9.00	*26.23	18.48	^a Brufen [GO]

■ NAPROXEN

Restricted benefit

Severe pain

Treatment criteria:

- Patient must be undergoing palliative care.

Clinical criteria:

- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

naproxen 125 mg/5 mL oral liquid, 474 mL

5397C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	3	..	121.66	40.30	Phebra Naproxen Suspension [FF]

■ NAPROXEN

Restricted benefit

Severe pain

Clinical criteria:

- Patient must be receiving palliative care.

naproxen 500 mg tablet, 50

5346J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.85	18.10	^a Inza 500 [AF]
			^B 1.12	17.97	18.10	^a Naprosyn [IX]

naproxen 750 mg modified release tablet, 28

5347K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.40	17.65	^a Proxen SR 750 [IY]
			^B 1.06	17.46	17.65	^a Naprosyn SR750 [IX]

naproxen 1 g modified release tablet, 28

5348L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	18.04	19.29	^a Proxen SR 1000 [IY]
			^B 1.12	19.16	19.29	^a Naprosyn SR1000 [IX]

naproxen 250 mg tablet, 50

5345H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*18.75	20.00	^a Inza 250 [AF]
			^B 2.24	*20.99	20.00	^a Naprosyn [IX]

■ NAPROXEN

Note Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

Restricted benefit

Severe pain

Clinical criteria:

- Patient must be receiving palliative care.

naproxen sodium 550 mg tablet, 50

5353R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	17.00	18.25	^a Crysanal [IY]
			^B 1.89	18.89	18.25	^a Anaprox 550 [IX]

■ NERVOUS SYSTEM

■ ANALGESICS

OPIOIDS

Natural opium alkaloids

MORPHINE

Caution The risk of drug dependence is high.

Note Telephone approvals are limited to 1 month's therapy.

Authority required

Chronic severe disabling pain

Clinical criteria:

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

morphine sulfate pentahydrate 200 mg modified release tablet, 28

5391R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	117.07	40.30	MS Contin [MF]

MORPHINE

Caution The risk of drug dependence is high.

Note Telephone approvals are limited to 1 month's therapy.

Authority required

Severe disabling pain

Clinical criteria:

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

morphine sulfate pentahydrate 20 mg tablet, 20

5394X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.92	21.17	Sevredol [MF]

morphine sulfate pentahydrate 10 mg tablet, 20

5393W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	19.10	20.35	Sevredol [MF]

MORPHINE

Caution The risk of drug dependence is high.

Morphine sulfate pentahydrate 10 and 20 mg modified release capsules must not be co-prescribed with immediate release oral morphine, when it has been prescribed for the reduction of chronic breathlessness.

Note Treatment should be initiated by a specialist knowledgeable in the use of potent opioids for the management of chronic breathlessness.

Note Applications for an increased maximum quantity to provide for 1 month's supply of this drug will be authorised.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Chronic Breathlessness

Clinical criteria:

- Patient must be receiving palliative care.

morphine sulfate pentahydrate 20 mg modified release capsule, 28

11761B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	28.40	29.65	Kapanol [YN]

morphine sulfate pentahydrate 10 mg modified release capsule, 28

11760Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	24.07	25.32	Kapanol [YN]

Phenylpiperidine derivatives

FENTANYL

Caution The risk of drug dependence is high.

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.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

Clinical criteria:

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

- Patient must be undergoing palliative care.

fentanyl 800 microgram sublingual tablet, 10

10612M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	87.70	40.30	Abstral [FK]

fentanyl 1200 microgram lozenge on handle, 9

5405L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	96.84	40.30	Actiq [TB]

fentanyl 200 microgram sublingual tablet, 10

10600X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*160.82	40.30	Abstral [FK]

fentanyl 800 microgram lozenge on handle, 9

5404K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	96.84	40.30	Actiq [TB]

fentanyl 1600 microgram lozenge on handle, 9

5406M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	96.84	40.30	Actiq [TB]

fentanyl 300 microgram sublingual tablet, 10

10606F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	87.70	40.30	Abstral [FK]

fentanyl 400 microgram sublingual tablet, 10

10603C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	87.70	40.30	Abstral [FK]

fentanyl 600 microgram sublingual tablet, 10

10604D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	87.70	40.30	Abstral [FK]

fentanyl 600 microgram lozenge on handle, 9

5403J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	96.84	40.30	Actiq [TB]

fentanyl 200 microgram lozenge on handle, 9

5401G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	96.84	40.30	Actiq [TB]

fentanyl 400 microgram lozenge on handle, 9

5402H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	96.84	40.30	Actiq [TB]

fentanyl 100 microgram sublingual tablet, 10

10601Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*160.82	40.30	Abstral [FK]

■ FENTANYL

Caution The risk of drug dependence is high.

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.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

Clinical criteria:

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

- Patient must be undergoing palliative care.

fentanyl 800 microgram orally disintegrating tablet, 4

10723J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*73.10	40.30	Fentora [TB]

fentanyl 200 microgram orally disintegrating tablet, 4

10697B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*73.10	40.30	Fentora [TB]

fentanyl 400 microgram orally disintegrating tablet, 4

10739F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*73.10	40.30	Fentora [TB]

fentanyl 100 microgram orally disintegrating tablet, 4

10729Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*73.10	40.30	Fentora [TB]

fentanyl 600 microgram orally disintegrating tablet, 4

10722H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*73.10	40.30	Fentora [TB]

▪ **FENTANYL**

Caution The risk of drug dependence is high.

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.

Note For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Telephone approvals are limited to 1 months' therapy.

Authority required

Breakthrough pain

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

- Patient must be undergoing palliative care.

fentanyl 1200 microgram lozenge on handle, 30

5411T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*575.84	40.30	Actiq [TB]

fentanyl 800 microgram sublingual tablet, 30

10611L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*462.32	40.30	Abstral [FK]

fentanyl 1600 microgram lozenge on handle, 30

5412W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*575.84	40.30	Actiq [TB]

fentanyl 300 microgram sublingual tablet, 30

10610K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*462.32	40.30	Abstral [FK]

fentanyl 800 microgram lozenge on handle, 30

5410R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*575.84	40.30	Actiq [TB]

fentanyl 600 microgram lozenge on handle, 30

5409Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*575.84	40.30	Actiq [TB]

fentanyl 200 microgram sublingual tablet, 30

10607G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*462.32	40.30	Abstral [FK]

fentanyl 200 microgram lozenge on handle, 30

5407N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*575.84	40.30	Actiq [TB]

fentanyl 400 microgram lozenge on handle, 30

5408P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*575.84	40.30	Actiq [TB]

fentanyl 100 microgram sublingual tablet, 30

10602B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*462.32	40.30	Abstral [FK]

fentanyl 400 microgram sublingual tablet, 30

10608H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*462.32	40.30	Abstral [FK]

fentanyl 600 microgram sublingual tablet, 30

10613N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*462.32	40.30	Abstral [FK]

■ FENTANYL

Caution The risk of drug dependence is high.

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.

Note For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Telephone approvals are limited to 1 months' therapy.

Authority required

Breakthrough pain

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

- Patient must be undergoing palliative care.

fentanyl 400 microgram orally disintegrating tablet, 28

10737D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*432.06	40.30	Fentora [TB]

fentanyl 800 microgram orally disintegrating tablet, 28

10738E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*432.06	40.30	Fentora [TB]

fentanyl 600 microgram orally disintegrating tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10713W	2	..	..	*432.06	40.30	Fentora [TB]

fentanyl 100 microgram orally disintegrating tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10684H	2	..	..	*432.06	40.30	Fentora [TB]

fentanyl 200 microgram orally disintegrating tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10698C	2	..	..	*432.06	40.30	Fentora [TB]

Diphenylpropylamine derivatives
■ METHADONE

Caution The risk of drug dependence is high.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Telephone approvals are limited to 1 month's therapy.

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.

Authority required

Chronic severe disabling pain

Treatment Phase: Initial treatment, for up to 3 months

Clinical criteria:

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

methadone hydrochloride 5 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5399E	1	2	..	23.09	24.34	Aspen Methadone Syrup [QA]

■ METHADONE

Caution The risk of drug dependence is high.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Telephone approvals are limited to 1 month's therapy.

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.

Authority required

Chronic severe disabling pain

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

methadone hydrochloride 5 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5400F	1	..	..	23.09	24.34	Aspen Methadone Syrup [QA]

Oripavine derivatives
■ BUPRENORPHINE

Caution The risk of drug dependence is high.

Note Telephone approvals are limited to 1 month's therapy.

Authority required

Chronic severe disabling pain

Clinical criteria:

- Patient must be receiving palliative care, **AND**
- The condition must be unresponsive to non-opioid analgesics.

buprenorphine 30 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10949G	2	2	..	*104.94	40.30	Norspan [MF]

buprenorphine 20 microgram/hour patch, 2

10970J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*82.36	40.30	^a Bupredermal [TX] ^a Norspan [MF]	^a Buprenorphine Sandoz [SZ]

buprenorphine 5 microgram/hour patch, 2

10957Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*38.98	40.23	^a Bupredermal [TX] ^a Norspan [MF]	^a Buprenorphine Sandoz [SZ]

buprenorphine 40 microgram/hour patch, 2

10959T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*127.52	40.30	Norspan [MF]	

buprenorphine 10 microgram/hour patch, 2

10948F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*58.52	40.30	^a Bupredermal [TX] ^a Norspan [MF]	^a Buprenorphine Sandoz [SZ]

buprenorphine 15 microgram/hour patch, 2

10953L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*70.42	40.30	^a Buprenorphine Sandoz [SZ] ^a Norspan [MF]	^a Norspan [MF]

buprenorphine 25 microgram/hour patch, 2

10964C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*93.64	40.30	Norspan [MF]	

OTHER ANALGESICS AND ANTIPYRETICS*Anilides***■ PARACETAMOL****Restricted benefit**

Analgesia or fever

Clinical criteria:

- Patient must be receiving palliative care, **AND**
- Patient must be intolerant to alternative therapy.

paracetamol 500 mg suppository, 24

5319Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	3	..	*82.43	40.30	Panadol [GC]	

■ PARACETAMOL

Note Pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 96 and pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 192 are equivalent for the purposes of substitution.

Restricted benefit

Analgesia or fever

Clinical criteria:

- Patient must be receiving palliative care, **AND**
- Patient must be intolerant to alternative therapy.

paracetamol 665 mg modified release tablet, 192

10796F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	18.94	20.19	^a Osteomol 665 Paracetamol [CR]	

paracetamol 665 mg modified release tablet, 96

5343F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*18.95	20.20	^a APOHEALTH Osteo Relief Paracetamol 665 mg [TX] ^a Osteomol 665 Paracetamol [CR]	^a Osteomol 665 Paracetamol [CR]

■ ANTIEPILEPTICS**ANTIEPILEPTICS***Benzodiazepine derivatives***■ CLONAZEPAM**

Note No increase in the maximum number of repeats may be authorised.

Authority required

Myoclonus

Clinical criteria:

- The treatment must be for prophylaxis or prevention of the indication, **AND**
- Patient must be receiving palliative care.

clonazepam 2 mg tablet, 100

5338Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	22.19	23.44	^a Paxam 2 [AF]
			^B 2.30	24.49	23.44	^a Rivotril [RO]

clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL

5339B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*18.99	20.24	Rivotril [RO]

CLONAZEPAM

Note Pharmaceutical benefits that have form pack size clonazepam 500 microgram tablet, 100 and clonazepam 500 microgram tablet, 50 are equivalent for the purposes of substitution.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Myoclonus

Clinical criteria:

- The treatment must be for prophylaxis or prevention of the indication, **AND**
- Patient must be receiving palliative care.

clonazepam 500 microgram tablet, 100

5337X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	17.18	18.43	^a Paxam 0.5 [AF]
			^B 1.84	19.02	18.43	^a Rivotril [RO]

clonazepam 500 microgram tablet, 50

11520H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	^B 1.84	*19.03	18.44	^a Rivotril [RO]

PSYCHOLEPTICS

ANXIOLYTICS

Benzodiazepine derivatives

DIAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Anxiety

Clinical criteria:

- Patient must be receiving palliative care.

diazepam 5 mg tablet, 50

5356X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	12.87	14.12	^a Antenex 5 [AF]	^a APO-Diazepam [TX]
						^a Valpam 5 [RW]	
			^B 3.30	16.17	14.12	^a Valium [RO]	

diazepam 2 mg tablet, 50

5355W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	12.80	14.05	^a APO-Diazepam [TX]	^a Valpam 2 [RW]
			^B 2.99	15.79	14.05	^a Antenex 2 [AF]	

OXAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Anxiety

Clinical criteria:

- Patient must be receiving palliative care.

oxazepam 15 mg tablet, 25

5371Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*14.33	15.58	^a Alepam 15 [AF]
			^B 5.32	*19.65	15.58	^a Serepax [QA]

oxazepam 30 mg tablet, 25

5372R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*13.65	14.90	^a Alepam 30 [AF]	^a APO-Oxazepam [TX]
						^a Murelax [RW]	

^B4.66 *18.31 14.90 ^a Serepax [QA]

HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

■ NITRAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving palliative care.

nitrazepam 5 mg tablet, 25

5359C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*14.71	15.96	^a Alodorm [AF]
			^B 2.48	*17.19	15.96	^a Mogadon [IL]

■ TEMAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Insomnia

Clinical criteria:

- Patient must be receiving palliative care.

temazepam 10 mg tablet, 25

5375X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*13.65	14.90	^a APO-Temazepam [TX]	^a Temaze [AF]
						^a Temtabs [FM]	
			^B 6.96	*20.61	14.90	^a Normison [QA]	

Repatriation Pharmaceutical Benefits Scheme

BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

Gold card

This card is issued to those veterans of Australia's defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.



White card

A White Card is issued to Australian veterans or mariners under the Veterans' Entitlements Act 1986 with:

- an accepted war or service-caused injury or disease;
- malignant cancer (neoplasia) whether war-caused or not;
- pulmonary tuberculosis whether war-caused or not;
- post-traumatic stress disorder whether war-caused or not; or
- anxiety and/or depression whether war-caused or not.



Orange card

Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who:

- have qualifying service from World War I or II and
- are aged 70 or over and
- have been resident in Australia for 10 years or more.



For more information go to the Department of Veterans' Affairs website:
<http://www.dva.gov.au>

RPBS Explanatory Notes

Introduction

The Australian Repatriation System

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
- Through the *Veterans' Entitlements Act 1986* the Department of Veterans' Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book. The prescriber shall ensure that a prescription contains the following details:
 - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
 - the patient's full name and address;
 - the prescription date;
 - the DVA file number of the patient as evidence of entitlement;
 - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
 - the item, form, strength, quantity and directions;
 - the number of repeats, if applicable;
 - indicate when brand substitution is not permitted; and
 - the name, signature, the prescriber number and address of the prescriber.

Prior Approval Arrangements

- The prior approval of the Department is required to prescribe the following:
 - 'Authority required' items (excluding 'Authority required (STREAMLINED)' items) listed in either the PBS or RPBS Schedule;
 - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
 - items listed under section 100 of the *National Health Act 1953*; and
 - other items not listed in either Schedule (non-Schedule items).
- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the *Schedule of Pharmaceutical Benefits* (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)
- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
 - using the Department's national free call number 1800 552 580; or
 - by mailing the written authority prescription to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
 - A current clinical report on the patient's condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
 - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
 - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
 - When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
 - Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
 - For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.
- Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
- A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. Medicare Australia will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans' Affairs for payment.

Palliative Care Drugs

- The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
 - clonazepam
 - cyclizine

- dexamethasone
- disodium pamidronate
- fentanyl
- glycopyrrolate
- hyoscine butylbromide
- hyoscine hydrobromide
- ketamine
- midazolam
- octreotide
- For further information telephone VAPAC on 1800 552 580.

Dental Prescribing

- Under Department of Veterans' Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled: Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
 - a Gold Repatriation Health Card – For All Conditions; or
 - a White Repatriation Health Card – For Specific Conditions; or
 - an Orange Repatriation Pharmaceutical Benefits Card.
- Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
- When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO's private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

Prescribing by optometrists

- Optometrists approved as 'PBS prescribers' may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
- Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe 'Authority required' optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.
- The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
- Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

Provisions governing pricing and payment for RPBS benefits

Introduction

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

Pricing of Schedule Items

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the *Schedule of Pharmaceutical Benefits*.

Pricing of Non-Schedule Ready Prepared Items

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than \$100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

Pricing of Non-Schedule Extemporaneously Prepared Items

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

Miscellaneous Pricing Rules

- The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
- If multiple quantities of a manufacturer's original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.

- When the quantity prescribed corresponds with the quantity of a manufacturer's original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.
- The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.
- For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

General

Packaging Material, Postage or Freight

- Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacist's itemised receipt.

Payment for Items Supplied at Short Intervals

- For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
- The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

Receipts for Patient Charges

- Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patient's name and address. The patient may apply for reimbursement from the Department.

Special Patient Contributions

- The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. Medicare Australia will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

Therapeutic Group Premiums — Authority Processing

- Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from Medicare Australia. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

Contact the Department of Veterans' Affairs

Authority Prescription Applications

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998

VAPAC (Veterans' Affairs Pharmaceutical Advisory Centre)

Department of Veterans' Affairs

GPO Box 9998

BRISBANE QLD 4001

For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is: 1800 552 580

Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.

WOUND ASSESSMENT AND DRESSING IDENTIFICATION

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.

This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.

Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound's healing process should be undertaken.

DRESSINGS

Pink Epithelialising Wound

Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

(A) Covering	- Film; - Film Island	- Gauze—Paraffin; - Non-adherent
(B) Absorbing	- Foam (Light Exudate); - Hydroactive (Superficial Wound—Light Exudate)	Hydrocolloid (Superficial Wound—Light Exudate)

Red Granulating Wound

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	- Foam (Light Exudate); - Hydroactive (Superficial Wound—Light Exudate); - Hydrocolloid (Superficial Wound—Light Exudate)	Hydrocolloid (Cavity Wound)
(B) Moisture donating	- Hydrogel—Amorphous; - Hydrogel—Sheet	Hydrogel—Amorphous
HIGH EXUDATE:	Superficial	Cavity
(A) Absorbing	- Alginate (Superficial Wound); - Foam—Heavy Exudate; - Hydroactive (Superficial Wound—Moderate Exudate); - Hydrocolloid (Superficial Wound—Moderate/High Exudate)	- Alginate (Cavity Wound); - Foam—Moderate Exudate (see “cavity conforming” product); - Hydroactive (Cavity Wound); - Hydrocolloid (Cavity Wound)
(B) Moisture donating	NOT APPROPRIATE	

Yellow Sloughy Wound

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	- Cadexomer Iodine; - Foam—Light Exudate; - Foam with Charcoal; - Hydroactive (Superficial Wound—Moderate Exudate); - Hydrocolloid (Superficial Wound—Moderate Exudate)	- Cadexomer Iodine; - Hydrocolloid (Cavity Wound)
(B) Moisture Donating	- Hydrogel—Amorphous; - Hydrogel—Sheet	Hydrogel—Amorphous
HIGH EXUDATE:	Superficial	Cavity
(A) Absorbing	- Alginate (Superficial Wound); - Cadexomer Iodine; - Foam—Heavy Exudate; - Hydroactive (Superficial Wound—Moderate/High Exudate); - Hydrocolloid (Superficial Wound—Moderate/High Exudate)	- Alginate (Cavity Wound); - Cadexomer Iodine; - Hydrocolloid (Cavity Wound)
(B) Moisture donating	NOT APPROPRIATE	

Black Necrotic Wound

Aims: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

DRY / LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	• Hydroactive (Superficial Wound—Light Exudate); • Hydrocolloid (Superficial Wound—Light/Moderate Exudate)	• Hydrocolloid (Cavity Wound)
(B) Moisture donating	• Hydrogel—Amorphous; • Hydrogel—Sheet	• Hydrogel—Amorphous; • Hydrogel—Sheet

Infected Wounds

Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

Malodorous Wounds

Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria in slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.

Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

Minor Skin Trauma

Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

Ordering Products

Ordering Coloplast Products

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

Ordering Hartmann Products

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

Ordering Molnlycke Healthcare Products

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

Ordering Smith & Nephew Products

Smith & Nephew products are distributed via the three major wholesalers, API, SIGMA & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

STOMATOLOGICAL PREPARATIONS

Antiinfectives and antiseptics for local oral treatment

CHLORHEXIDINE

chlorhexidine gluconate 0.2% mouthwash, 250 mL

4161B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	16.24	6.50	Plaqacide [OB]

chlorhexidine gluconate 0.2% mouthwash, 300 mL

4204G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	19.18	6.50	Savacol Mouth and Throat Rinse [OM]

NYSTATIN

nystatin 100 000 units/mL oral liquid, 24 mL

10854G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	17.96	6.50	^a Pharmacy Action Nystatin Oral Drops [GQ]
			..	19.20	6.50	^a Mycostatin Oral Drops [QA]

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

Synthetic anticholinergics, esters with tertiary amino group

MEBEVERINE

mebeverine hydrochloride 135 mg tablet, 90

4328T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	29.30	6.50	^a APO-Mebeverine [TX]	^a Colese [AF]
			..	33.80	6.50	^a Colofac [GO]	

BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, semisynthetic, quaternary ammonium compounds

HYOSCINE BUTYLBROMIDE

hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

4279F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	23.82	6.50	^a Buscopan [VZ]	^a HYOSCINE BUTYLBROMIDE SXP [XC]

DRUGS FOR CONSTIPATION

DRUGS FOR CONSTIPATION

Softeners, emollients

DOCUSATE

docusate sodium 50 mg tablet, 100

4200C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	18.34	6.50	Coloxyl 50 [FM]

Contact laxatives

BISACODYL

bisacodyl 10 mg suppository, 12

10580W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	4	..	*21.82	6.50	Petrus Bisacodyl Suppositories [PP]

bisacodyl 10 mg suppository, 10

10578R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*24.10	6.50	^a Petrus Bisacodyl Suppositories [PP]
			..	*25.39	6.50	^a Dulcolax [VZ]

■ **DOCUSATE + SENNOSIDE B****docusate sodium 50 mg + sennoside B 8 mg tablet, 90**

10177P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	17.32	6.50	Pharmacy Action Laxative with Senna [GQ]

docusate sodium 50 mg + sennoside B 8 mg tablet, 100

4028B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	18.43	6.50	Soflax [EA]

■ **DOCUSATE + SENNOSIDES****docusate sodium 50 mg + sennosides 11.27 mg tablet, 90**

4198Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	17.36	6.50	^a Chemists' Own Laxative with Senna [RW]	^a Colaxsen [QA]
			..	20.41	6.50	^a Co-Senna [PP]	^a Coloxyl with Senna [FM]

■ **SENNOSIDE B****sennoside B 7.5 mg tablet, 100**

4455L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	16.85	6.50	^a Senna-Gen [PP]
			..	17.95	6.50	^a Senokot [RC]

Bulk-forming laxatives■ **DRY PSYLLIUM HUSK****dry psyllium husk 3.5 g powder for oral liquid, 30 sachets**

4285M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	21.24	6.50	Fybogel [RC]

■ **PSYLLIUM HUSK POWDER****PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (non-flavoured) 336 g, 1**

4422R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	21.57	6.50	Fibre Health Natural Granular [PP]
			..	24.74	6.50	Metamucil Natural Granular [PY]

PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (orange-flavoured, sugar-free) 283 g, 1

4419N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	24.74	6.50	Metamucil Orange Smooth [PY]

■ **RHAMNUS FRANGULA + STERCULIA****rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g**

4558X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	25.58	6.50	Normacol Plus [NE]

Enemas■ **CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL****sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 4 x 5 mL**

4462W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	16.42	6.50	Micolette [AE]

Other drugs for constipation■ **GLYCEROL****glycerol 2.8 g suppository, 12**

4246L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*24.19	6.50	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 700 mg suppository, 12

10586E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*23.35	6.50	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 1.4 g suppository, 12

10596Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*23.71	6.50	Petrus Pharmaceuticals Pty Ltd [PP]

■ ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

ELECTROLYTES WITH CARBOHYDRATES

Oral rehydration salt formulations

■ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID

sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets

10574M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	16.29	6.50	restore O.R.S. [EA]

ANTIPROPULSIVES

Antipropulsives

■ LOPERAMIDE

loperamide hydrochloride 2 mg capsule, 20

11135C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	12.97	6.50	Pharmacy Action Diarrhoea Relief [GQ]

loperamide hydrochloride 2 mg capsule, 12

10592L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	12.97	6.50	Gastrex [CR]

■ ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS

ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS

Peripherally acting antiobesity products

■ ORLISTAT

Note The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.

Authority required

Obesity

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; OR
 - Patient must have a BMI greater than or equal to 30 with 1 or more of the following co-morbidities;(i) diabetes;(ii) ischaemic heart disease;(iii) psychiatric conditions;(iv) hypertension, **AND**
 - Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available), **AND**
 - The treatment must not exceed 12 months in total from initial application, **AND**
 - Patient must not receive more than 1 continuous treatment in a lifetime.
- The prescriber must provide the patient's initial body weight and BMI at the time of application.

Authority required

Obesity

Treatment Phase: Continuing treatment (3 to 6 months following commencement)

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their initial body weight by 2.5 kg or 2.5% (whichever is the lesser) during the period 3 to 6 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

Authority required

Obesity

Treatment Phase: Continuing treatment (6 to 12 months following commencement)

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their initial body weight by 5 kg or 5% (whichever is the lesser) during the period 6 to 12 months following commencement of treatment with this drug, **AND**

- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

orlistat 120 mg capsule, 84

4570M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	133.06	6.50	Xenical [RO]

■ VITAMINS

VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

Vitamin B1, plain

■ THIAMINE

thiamine hydrochloride 100 mg tablet, 100

4043T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	15.37	6.50	Betavit [PP]

VITAMIN B-COMPLEX, INCL. COMBINATIONS

Vitamin B-complex, plain

■ LYSINE + THIAMINE + PYRIDOXINE + CYANOCOBALAMIN + FERRIC PYROPHOSPHATE

lysine hydrochloride 300 mg/10 mL + thiamine hydrochloride 10 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL oral liquid, 200 mL

4493L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	17.50	6.50	Accomin Adult Tonic [PF]

■ MINERAL SUPPLEMENTS

CALCIUM

Calcium

■ CALCIUM

Restricted benefit

Hyperphosphataemia

Clinical criteria:

- The condition must be associated with chronic renal failure.

CALCIUM Tablet 600 mg (as carbonate), 120

4142B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*22.63	6.50	CAL-600 [PP]

CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

4094L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	1	..	*27.35	6.50	Cal-500 [PP]

■ CALCIUM

Restricted benefit

Hypocalcaemia

Restricted benefit

Osteoporosis

Restricted benefit

Proven calcium malabsorption

CALCIUM Tablet 600 mg (as carbonate), 120

4082W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	17.05	6.50	CAL-600 [PP]

CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

4333C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*19.43	6.50	Cal-500 [PP]

OTHER MINERAL SUPPLEMENTS

Magnesium

■ MAGNESIUM ASPARTATE DIHYDRATE

Restricted benefit

Hypomagnesaemia

The condition must be documented in the patient's medical records.

magnesium aspartate dihydrate 500 mg (magnesium 37.4 mg) tablet, 50

4321K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	17.50	6.50	Amcal Mag-A [IG] Pharmacy Care Magnesium [SI]	Mag-Sup [PP]
			..	18.07	6.50	Magmin [BB]	

■ BLOOD AND BLOOD FORMING ORGANS

■ ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Platelet aggregation inhibitors excl. heparin

■ ASPIRIN

aspirin 100 mg tablet, 90

4076M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	19.52	6.50	Cardiprin 100 [RC]

aspirin 100 mg tablet, 112

10590J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	13.32	6.50	Spren 100 [OW]

■ ASPIRIN

Note The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

aspirin 100 mg enteric capsule, 84

4078P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	18.61	6.50	Astrix [YN]

aspirin 100 mg enteric tablet, 84

4077N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	17.82	6.50	Cardasa [AF] ^a Cartia [AS]	^a Pharmacy Action Low Dose Aspirin [GQ]

■ CLOPIDOGREL

Note Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

Authority required

For use in patients pre- and post-angioplasty

clopidogrel 75 mg tablet, 28

10169F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	15.57	6.50	^a Clopidogrel GH [GQ]	^a Plidogrel [RF]

clopidogrel 75 mg tablet, 28

4179Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	15.57	6.50	^a APO-Clopidogrel [TX] ^a Chem mart Clopidogrel [CH] ^a Iscover [AV] ^a Plavix [SW]	^a Blooms the Chemist Clopidogrel [IB] ^a Clopidogrel AN [EA] ^a Piax [AF] ^a Terry White Chemists Clopidogrel [TW]

■ ANTIANEMIC PREPARATIONS

IRON PREPARATIONS

Iron bivalent, oral preparations

■ FERROUS FUMARATE

ferrous fumarate 200 mg (iron 65.7 mg) tablet, 60

10594N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	18.15	6.50	Ferro-tab [AE]

BLOOD AND BLOOD FORMING ORGANS

Iron in combination with folic acid

■ FERROUS FUMARATE + FOLIC ACID

ferrous fumarate 310 mg (iron 100 mg) + folic acid 350 microgram tablet, 60

10579T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	19.17	6.50	Ferro-f-tab [AE]

VITAMIN B12 AND FOLIC ACID

Vitamin B12 (cyanocobalamin and analogues)

■ HYDROXOCOBALAMIN

Note One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B₁₂ deficiencies.

Note Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

Restricted benefit

Pernicious anaemia

Restricted benefit

Proven vitamin B12 deficiencies other than pernicious anaemia

Restricted benefit

Anaemias associated with vitamin B12 deficiency

Clinical criteria:

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

10577Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	15.75	6.50	^a Vita-B12 [GH]

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

10587F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	15.75	6.50	^a Neo-B12 [PF]

Folic acid and derivatives

■ FOLIC ACID

folic acid 500 microgram tablet, 100

10584C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*15.55	6.50	^a Foltabs 500 [PP]	^a Megafol 0.5 [AF]

■ FOLIC ACID

Note The 5 mg strength tablet should be used in malabsorption states only.

folic acid 5 mg tablet, 100

10573L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*17.77	6.50	Megafol 5 [AF]

■ BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

IRRIGATING SOLUTIONS

Salt solutions

■ SODIUM CHLORIDE

sodium chloride 0.9% (4.5 g/500 mL) solution, 500 mL bottle

4460R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	14.88	6.50	Baxter Healthcare Pty Ltd [BX]

sodium chloride 0.9% (9 g/L) solution, 1 L bottle

4461T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	15.16	6.50	Baxter Healthcare Pty Ltd [BX]

CARDIOVASCULAR SYSTEM

VASOPROTECTIVES

AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE

Other agents for treatment of hemorrhoids and anal fissures for topical use

ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE

zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository, 12

4040P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	17.51	6.50	Anusol [JT]

zinc oxide 10.75% + peru balsam 1.88% + benzyl benzoate 1.25% ointment, 50 g

4039N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	18.45	6.50	Anusol [JT]

DERMATOLOGICALS

ANTIFUNGALS FOR DERMATOLOGICAL USE

ANTIFUNGALS FOR TOPICAL USE

Antibiotics

NYSTATIN

nystatin 100 000 units/g cream, 15 g

4001N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	15.76	6.50	Mycostatin [FM]

Imidazole and triazole derivatives

CLOTRIMAZOLE

clotrimazole 1% cream, 20 g

4004R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	13.24	6.50	^a Pharmacy Action Anti-Fungal Cream [GQ]
			..	13.58	6.50	^a Clonea [AF]

Other antifungals for topical use

AMOROLFINE

Restricted benefit

Onychomycosis

amorolfine 5% solution, 5 mL

4010C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	48.04	6.50	^a Myconail [AE]
			..	68.12	6.50	^a Pharmacy Action Anti-Fungal Nail Treatment [GQ]
			..	84.29	6.50	^a Aporyl [TX]
			..	93.04	6.50	^a Loceryl [GA]

TERBINAFINE

Restricted benefit

Tinea pedis

terbinafine hydrochloride 1% cream, 15 g

4473K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	1	..	24.93	6.50	^a Lamisil [GK]	^a Pharmacy Action Pharmsil [GQ]

terbinafine 1% gel, 15 g

4463X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	26.20	6.50	Lamisil DermGel [GK]

TOLNAFTATE

tolnaftate 0.07% spray, 100 g

4481W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	19.02	6.50	Tinaderm [BN]

ANTIFUNGALS FOR SYSTEMIC USE

Antifungals for systemic use

■ TERBINAFINE

Authority required

Onychomycosis

Clinical criteria:

- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

terbinafine 250 mg tablet, 42

4011D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	30.39	6.50	^a APO-Terbinafine [TX] ^a Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV] ^a Terbinafine GH [GQ] ^a Tinasil [AF]	^a GenRx Terbinafine [GX] ^a Tamsil [RW] ^a Terbinafine Sandoz [SZ]

■ EMOLLIENTS AND PROTECTIVES

EMOLLIENTS AND PROTECTIVES

Soft paraffin and fat products

■ WOOL ALCOHOLS

wool alcohols 6% ointment, 100 g

4041Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	18.23	6.50	Eucerin [BE]

Carbamide products

■ UREA

urea 10% cream, 100 g

4042R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	16.50	6.50	Aquacare H.P. [AG]
			..	16.72	6.50	Urederm [KY]
			..	17.00	6.50	Calmurid [OL]

Other emollients and protectives

■ GELATIN + PECTIN + CARMELLOSE SODIUM

gelatin 16.7% + pectin 16.7% + carmellose sodium 16.7% paste, 5 g

4518T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	16.20	6.50	Orabase [QA]

■ GLYCEROL + WHITE SOFT PARAFFIN

glycerol 5% + white soft paraffin 5% lotion, 1 L

11712K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	30.68	6.50	QV Skin Lotion [EO]

■ SKIN EMOLLIENT

SKIN EMOLLIENT Lotion 500 mL, 1

4107E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	20.98	6.50	Alpha Keri Lotion [MT]

SKIN EMOLLIENT Bath oil 500 mL, 1

4122Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	20.98	6.50	Alpha Keri Bath Oil [MT]
			..	23.08	6.50	QV Bath Oil [EO]
			..	23.16	6.50	Hamilton Skin Therapy Oil [KY]

PROTECTIVES AGAINST UV-RADIATION

Protectives against UV-radiation for topical use

■ BEMOTRIZINOL + OCTOCRYLENE + DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE + TITANIUM DIOXIDE

bemotrizinol 1% + octocrylene 2% + diethylamino hydroxybenzoyl hexyl benzoate 3.5% + titanium dioxide 2% lotion, 125 mL

11387H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	21.59	6.50	Sunsense Ultra SPF 50+ [EO]

■ SUNSCREENS

SUNSCREENS Lotion (non-alcoholic) 125 mL, 1

4546G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	19.79	6.50	Aquasun Lotion SPF 18 [PF]

SUNSCREENS Cream 75 g, 1

4307Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	21.59	6.50	Sunsense Sensitive SPF 50+ [EO]

■ ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

Anesthetics for topical use

■ LIDOCAINE (LIGNOCAINE)

lidocaine (lignocaine) hydrochloride 2% oral liquid, 200 mL

4308R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	103.60	6.50	Xylocaine Viscous [QA]

Other antipruritics

■ TAR + TROLAMINE LAURIL SULFATE

Note For patients who have failed to respond to simple moisturising agents.

tar 2.3% + trolamine lauril sulfate 6% solution, 500 mL

4408B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	25.83	6.50	Pinetarsol [EO]

■ ANTIPSORIATICS

ANTIPSORIATICS FOR TOPICAL USE

Tars

■ COAL TAR SOLUTION + PHENOL + PRECIPITATED SULFUR

coal tar solution 5% + phenol 0.5% + precipitated sulfur 0.5% gel, 30 g

4505D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	19.83	6.50	Egopsoryl-TA [EO]

■ ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

ANTIBIOTICS FOR TOPICAL USE

Other antibiotics for topical use

■ MUPIROCIN

Restricted benefit

Secondarily infected traumatic skin lesions

mupirocin 2% ointment, 15 g

4350Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±1	..	..	20.90	6.50	^a APO-Mupirocin [TX]	^a Bactroban [GK]

mupirocin 2% cream, 15 g

4348W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	20.90	6.50	Bactroban [GK]

CHEMOTHERAPEUTICS FOR TOPICAL USE

Other chemotherapeutics

DERMATOLOGICALS

■ INGENOL MEBUTATE

Authority required

Solar keratosis

Clinical criteria:

- Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

ingenol mebutate 0.015% gel, 3 x 470 mg

2464Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	139.29	6.50	Picato [LO]

■ INGENOL MEBUTATE

Authority required

Solar (actinic) keratosis

Clinical criteria:

- Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

ingenol mebutate 0.05% gel, 2 x 470 mg

2468X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	139.29	6.50	Picato [LO]

■ CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

CORTICOSTEROIDS, PLAIN

Corticosteroids, weak (group I)

■ HYDROCORTISONE ACETATE

hydrocortisone acetate 1% cream, 30 g

11710H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	16.65	6.50	Pharmacy Action Hydrocortisone Cream 1% [GQ]

■ HYDROCORTISONE ACETATE

Restricted benefit

Corticosteroid-responsive dermatoses

hydrocortisone acetate 1% ointment, 30 g

10831C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	16.65	6.50	Cortic-DS 1% [QA]

Corticosteroids, potent (group III)

■ BETAMETHASONE VALERATE

betamethasone (as valerate) 0.1% ointment, 30 g

4132L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	25.40	6.50	Betnovate [QA]

betamethasone (as valerate) 0.1% cream, 30 g

4131K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	25.40	6.50	Betnovate [QA]

■ MOMETASONE

Note Application to large areas of skin for longer than four weeks is not recommended.

mometasone furoate 0.1% ointment, 50 g

4343N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	..	..	35.01	6.50	^a Elocon [MK]	^a Momasone [QA]

mometasone furoate 0.1% cream, 50 g

4342M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	35.01	6.50	Elocon [MK]

■ ANTISEPTICS AND DISINFECTANTS

ANTISEPTICS AND DISINFECTANTS

Iodine products

POVIDONE-IODINE

povidone-iodine 10% solution, 100 mL

4411E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	25.12	6.50	Betadine Antiseptic Liquid [SW]

OTHER DERMATOLOGICAL PREPARATIONS

OTHER DERMATOLOGICAL PREPARATIONS

Medicated shampoos

SALICYLIC ACID + BENZALKONIUM CHLORIDE + ALCOHOL + COAL TAR SOLUTION + POLYOXYETHYLENE ETHERS

SALICYLIC ACID with COAL TAR SOLUTION Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL, 1

4560B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	23.62	6.50	Ionil-T [GA]

SELENIUM SULFIDE

selenium sulfide 2.5% shampoo, 125 mL

4452H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	18.19	6.50	Selsun [DQ]

TAR + COAL TAR SOLUTION + SALICYLIC ACID

tar 1% + coal tar solution 1% + salicylic acid 2% solution, 250 mL

4447C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	22.28	6.50	Sebitar [EO]

Wart and anti-corn preparations

SALICYLIC ACID + LACTIC ACID

salicylic acid 16.7% + lactic acid 16.7% solution, 15 mL

4386W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	21.68	6.50	Duofilm Solution [GK]

Other dermatologicals

DICLOFENAC

Note Maximum quantity of four tubes (original + 3 repeats) in 12 months.

Authority required

Solar (actinic) keratosis

Treatment Phase: Management

Clinical criteria:

- Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

diclofenac sodium 3% gel, 25 g

4046Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	58.54	6.50	Solaraze 3% Gel [FK]

GLYCEROL

glycerol 15% solution, 1 kg

11708F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	30.19	6.50	QV Gentle Wash [EO]

ICHTHAMMOL

Note For patients who have failed to respond to simple moisturising agents.

ichthammol 1% cream, 50 g

4281H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	21.64	6.50	Egoderma Cream [EO]

ICHTHAMMOL + ZINC OXIDE

Note For patients who have failed to respond to simple moisturising agents.

GENITO URINARY SYSTEM AND SEX HORMONES

ichthammol 1% + zinc oxide 15% ointment, 50 g

4280G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	21.64	6.50	Egoderim Ointment [EO]

■ IMIQUIMOD

Authority required

Superficial basal cell carcinoma

Treatment Phase: Primary treatment

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The condition must be one where other standard treatments are inappropriate, **AND**
- The condition must require topical drug therapy.

imiquimod 5% cream, 12 x 250 mg sachets

4559Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	87.01	6.50	^a Aldiq [QA]	^a APO-Imiquimod [TX]
			..	89.29	6.50	^a Aldara [IL]	

■ IMIQUIMOD

Note Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

Authority required

Solar keratosis

Clinical criteria:

- Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

imiquimod 5% cream, 12 x 250 mg sachets

4134N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	87.01	6.50	^a Aldiq [QA]	^a APO-Imiquimod [TX]
			..	89.29	6.50	^a Aldara [IL]	

imiquimod 5% cream, 2 x 2 g

10106X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	91.56	6.50	^a Aldara Pump [IL]

■ LIGHT LIQUID PARAFFIN + COCOAMPHODIACETATE DISODIUM

light liquid paraffin 3.5% + cocoamphodiacetate disodium 3% lotion, 500 mL

4549K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	23.93	6.50	Hamilton Skin Therapy Wash [KY]

■ PANTHENOL

Note To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).

panthenol conditioner, 200 g

4510J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	18.29	6.50	SebiRinse [EO]

■ ZINC OXIDE + MAIZE STARCH + PURIFIED TALC + CHLORPHENESIN

zinc oxide 25% + maize starch 55.85% + purified talc 18.07% + chlorphenesin 1% powder, 100 g

4497Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	16.55	6.50	Z.S.C. [RW]

■ GENITO URINARY SYSTEM AND SEX HORMONES

■ GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS

Antibiotics

■ NYSTATIN

nystatin 20 000 units/g vaginal cream, 75 g

4013F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	17.89	6.50	Nilstat [QA]

Imidazole derivatives

■ CLOTRIMAZOLE

clotrimazole 2% vaginal cream, 20 g

4017K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	..	..	19.01	6.50	APO-Clotrimazole 3 Day Cream [TX]	Clonea 3 Day Cream [AF]

clotrimazole 1% vaginal cream, 35 g

4016J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	..	..	17.80	6.50	^a Clonea 6 Day Cream [AF]	^a Pharmacy Action FemCream [GQ]
			..	19.01	6.50	^a APO-Clotrimazole 6 Day Cream [TX]	

■ OTHER GYNECOLOGICALS

OTHER GYNECOLOGICALS

■ ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID

acetic acid 0.94% + oxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g

4434J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	34.51	6.50	Aci-Jel [CU]

■ UROLOGICALS

UROLOGICALS

Drugs used in erectile dysfunction

■ ALPROSTADIL

Authority required

Erectile dysfunction

Clinical criteria:

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

Population criteria:

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

alprostadil 20 microgram injection [2] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack

4580C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*133.27	6.50	Caverject Impulse [PF]

alprostadil 10 microgram injection [2] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack

4579B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*106.03	6.50	Caverject Impulse [PF]

■ SILDENAFIL

Authority required

Erectile dysfunction

Clinical criteria:

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

Population criteria:

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

sildenafil 100 mg tablet, 4

4586J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	72.00	6.50	^a APO-Sildenafil [TX]	^a Chem mart Sildenafil [CH]
						^a Sildenafil Actavis [EA]	^a Sildenafil generichealth [GQ]
						^a Terry White Chemists Sildenafil [TW]	^a Vasafil 100 [RW]
						^a Vedafile [AF]	
			..	83.53	6.50	^a Viagra [PF]	

GENITO URINARY SYSTEM AND SEX HORMONES

sildenafil 25 mg tablet, 4

4584G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	55.43	6.50	^a Sildenafil Actavis [EA]	^a Vasafil 25 [RW]
			..	55.44	6.50	^a Vedafile [AF]	
			..	63.81	6.50	^a APO-Sildenafil [TX]	
						^a Viagra [PF]	

sildenafil 50 mg tablet, 4

4585H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	67.43	6.50	^a APO-Sildenafil [TX]	^a Sildenafil Actavis [EA]
						^a Vasafil 50 [RW]	^a Vedafile [AF]
			..	78.09	6.50	^a Viagra [PF]	

■ TADALAFIL

Authority required

Erectile dysfunction

Clinical criteria:

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

Population criteria:

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

tadalafil 10 mg tablet, 4

4596X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	104.24	6.50	Cialis [LY]

tadalafil 20 mg tablet, 4

4597Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	104.24	6.50	Cialis [LY]

■ VARDENAFIL

Authority required

Erectile dysfunction

Clinical criteria:

- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

Population criteria:

- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

varденаfil 20 mg tablet, 4

4302K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	81.57	6.50	Levitra [BN]

varденаfil 10 mg tablet, 4

4290T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	71.82	6.50	Levitra [BN]

Other urologicals

■ BICARBONATE + CITRIC ACID + TARTARIC ACID

Restricted benefit

Urinary symptoms

Clinical criteria:

- The treatment must be for when antibiotic or other therapy alone is inappropriate.

sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid, 28 x 4 g sachets

4049D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	4	..	17.68	6.50	Uracol [EA]	Ural Sachets [QA]

DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

Alpha-adrenoreceptor antagonists

■ ALFUZOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

alfuzosin hydrochloride 10 mg modified release tablet, 30

4277D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	63.24	6.50	Xatral SR [SW]

■ DUTASTERIDE + TAMSULOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30

10102Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	32.36	6.50	Duodart 500ug/400ug [GK]

■ TAMSULOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

tamsulosin hydrochloride 400 microgram modified release tablet, 30

4070F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	63.24	6.50	Flomaxtra [LS]	Tamsulosin Sandoz SR [SZ]

Testosterone-5-alpha reductase inhibitors

■ DUTASTERIDE

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

dutasteride 500 microgram capsule, 30

10095H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	28.15	6.50	^a APO-Dutasteride [TX]
			..	35.15	6.50	^a Avodart [GK]

■ FINASTERIDE

Authority required

Benign prostatic hyperplasia

Clinical criteria:

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

finasteride 5 mg tablet, 30

4233T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	76.27	6.50	^a Auro-Finasteride [DO]	^a Finasteride AN [EA]
			..	94.12	6.50	^a Finasteride GH 5 [GQ]	^a Finide [AL]
			..	98.47	6.50	^a Finnacar [RW]	^a Finasta [SZ]
						^a APO-Finasteride [TX]	^a Pharmacor Finasteride 5 [CR]
						^a Finasteride-GA 5 [GN]	
						^a Proscar [MK]	

finasteride 5 mg tablet, 28

4303L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	88.61	6.50	^a Finpro [RZ]	^a Pharmacy Choice Finasteride [RI]

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

Restricted benefit

Upper and lower respiratory tract infections

azithromycin 500 mg tablet, 3

4115N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	33.30	6.50	Zedd 500 [RW]	
						^a APO-Azithromycin [TX]	^a Azithromycin-GA [EA]
						^a Azithromycin Mylan [AF]	^a Azithromycin Sandoz [SZ]
						^a Chem mart Azithromycin [CH]	^a Terry White Chemists
							Azithromycin [TW]
						^a ZITHRO [RF]	^a Zithromax [PF]
						^a Zitrocin [GN]	

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

FLUOROURACIL

fluorouracil 5% cream, 20 g

4222F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	..	..	65.67	6.50	^a APOC-5FU [TX]	^a Efudix [IL]

IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Tumor necrosis factor alpha (TNF-) inhibitors

INFLIXIMAB

Note Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

Reply Paid 9998

Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)

Department of Veterans' Affairs

GPO Box 9998

BRISBANE QLD 4001

Authority required

Initial treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Initial treatment may be prescribed by rheumatologists or consultant physicians for the reduction of signs and symptoms and prevention of structural joint damage in adult patients with active rheumatoid arthritis who satisfy all of the following criteria:

- (1) (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and
- (1) (b) Proven erosive rheumatoid arthritis without end-stage disease;
- (2) Failure of an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or cyclosporin) — unless these drugs were contraindicated or intolerance had developed;
- (3) No history of active tuberculosis requiring treatment in the last 3 years;
- (4) No history of opportunistic infection in the last 2 months;
- (5) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

Authority required

Continuing treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Continuing treatment may be prescribed by rheumatologists or consultant physicians, following initial therapy of 3 doses, in patients who satisfy the following criteria:

- (1) There is improvement in ESR and/or CRP; and

- (2) An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy. Applications for authorisation must be in writing and must include:
- (1) a completed authority prescription form; and
 - (2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

infliximab 100 mg injection, 1 vial

4284L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	504.41	6.50	Remicade [JC]

■ MUSCULO-SKELETAL SYSTEM

■ TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

Preparations with salicylic acid derivatives

■ METHYL SALICYLATE

methyl salicylate 50% ointment, 100 g

4023R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	16.48	6.50	Gold Cross [BI]

methyl salicylate 25% liniment, 100 mL

4026X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	14.54	6.50	Gold Cross [BI]

■ METHYL SALICYLATE + EUCALYPTUS OIL + MENTHOL

methyl salicylate 25% + eucalyptus oil 10% + menthol 4% cream, 100 g

4022Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	18.09	6.50	Gold Cross [BI]

■ METHYL SALICYLATE + MENTHOL + CAMPHOR + EUCALYPTUS OIL + PINE OIL PUMILIO + TURPENTINE OIL + PEPPERMINT OIL + CAJUPUT OIL + CAPSICUM ANNUUM

methyl salicylate 20% + menthol 5% + camphor 3.5% + eucalyptus oil 3% + pine oil pumilio 1% + turpentine oil 1% + peppermint oil 0.5% + cajuput oil 0.5% + capsicum annuum 0.15% cream, 100 g

11707E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	18.09	6.50	Goanna Heat Cream [GQ]

■ DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

■ RISEDRONATE

Authority required

Preservation of bone mineral density

Clinical criteria:

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

risedronate sodium 5 mg tablet, 28

4443W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	35.49	6.50	Actonel [TT]

risedronate sodium 35 mg tablet, 4

4444X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	35.49	6.50	^a Acris Once-a-Week [AF] ^a Risedronate AN [EA] ^a Risedronate Sandoz [SZ]	^a APO-Risedronate [TX] ^a Risedronate-GA [GN] ^a Risedro once a week [RW]

risedronate sodium 35 mg enteric tablet, 4

2191H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	35.49	6.50	Actonel EC [TT]

Bisphosphonates, combinations

NERVOUS SYSTEM

■ ALENDRONATE + COLECALCIFEROL

Authority required

Preservation of bone mineral density

Clinical criteria:

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

2224C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	18.33	6.50	^a Alendronate plus D3-DRLA [RZ]	^a APO-Alendronate Plus D3 70 mg/140 mcg [TX]
			..	22.33	6.50	^a FonatPlus [AF] ^a Fosamax Plus 70 mg/140 mcg [MK]	

alendronate 70 mg + colecalciferol 70 microgram tablet, 4

2194L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	18.33	6.50	^a Alendronate plus D3-DRLA [RZ]	^a APO-Alendronate Plus D3 70 mg/70 mcg [TX]
			..	22.33	6.50	^a FonatPlus [AF] ^a Fosamax Plus [MK]	

■ RISEDRONATE (&) CALCIUM CARBONATE

Authority required

Preservation of bone mineral density

Clinical criteria:

- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28

4059P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	35.49	6.50	Acris Combi [AF]

■ NERVOUS SYSTEM

■ ANALGESICS

OPIOIDS

Natural opium alkaloids

■ MORPHINE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- chronic severe disabling pain associated with proven malignant neoplasia; or
- chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

morphine sulfate pentahydrate 200 mg modified release tablet, 28

4349X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	117.07	6.50	MS Contin [MF]

Opioids in combination with non-opioid analgesics

■ ASPIRIN + CODEINE

aspirin 300 mg + codeine phosphate hemihydrate 8 mg dispersible tablet, 40

4286N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	18.23	6.50	Aspalgin 40 [QA]

■ **PARACETAMOL + CODEINE****paracetamol 500 mg + codeine phosphate hemihydrate 8 mg tablet, 40**

4275B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	15.19	6.50	Panamax Co. 40 [SW]

OTHER ANALGESICS AND ANTIPYRETICS*Anilides*■ **PARACETAMOL****paracetamol 500 mg tablet, 100**

10582Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	13.13	6.50	^a APO-Paracetamol [TX] ^a Panamax [SW] ^a Paracetamol (Sandoz) [SZ] ^a Parapane [AF]	^a Febridol [EA] ^a Paracetamol Generic Health [GQ] ^a Paralgin [OW]

paracetamol 240 mg/5 mL oral liquid, 200 mL

10599W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	15.18	6.50	Panamax 240 Elixir [SW]

■ **PARACETAMOL****Restricted benefit**

Persistent pain

Clinical criteria:

- The condition must be associated with osteoarthritis.

paracetamol 665 mg modified release tablet, 96

10598T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*18.95	6.50	^a Osteomol 665 Paracetamol [CR]	^a Pharmacy Action Paracetamol Osteo 665 [GQ]

■ **PARACETAMOL****Restricted benefit**

Chronic arthropathies

paracetamol 500 mg tablet, 100

10585D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	4	..	*16.42	6.50	^a APO-Paracetamol [TX] ^a Panamax [SW] ^a Paracetamol (Sandoz) [SZ] ^a Parapane [AF]	^a Febridol [EA] ^a Paracetamol Generic Health [GQ] ^a Paralgin [OW]

Other analgesics and antipyretics■ **GABAPENTIN****Authority required**

Refractory neuropathic pain

Clinical criteria:

- The condition must be unable to be controlled by other drugs.

gabapentin 300 mg capsule, 100

4592Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	24.98	6.50	^a APO-Gabapentin [TX] ^a Gabapentin APOTEX [TY] ^a Gabapentin GH [GQ] ^a GenRx Gabapentin [GX] ^a Nupentin 300 [AF]	^a Gabapentin 300 [CR] ^a Gabapentin Aspen 300 [RW] ^a Gantin [EA] ^a Neurontin [PF]

gabapentin 800 mg tablet, 100

4595W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	50.45	6.50	^a APO-Gabapentin [TX] ^a Gabapentin APOTEX [TY] ^a Gantin [ED] ^a Neurontin [PF]	^a Gabapentin AN [EA] ^a Gabapentin Aspen 800 [RW] ^a GenRx Gabapentin [GX]

gabapentin 400 mg capsule, 100

4593R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	29.89	6.50	^a APO-Gabapentin [TX] ^a Gabapentin APOTEX [TY]	^a Gabapentin 400 [CR] ^a Gabapentin Aspen 400 [RW]

^a Gabapentin GH [GQ]
^a GenRx Gabapentin [GX]
^a Nupentin 400 [AF]

^a Gantin [EA]
^a Neurontin [PF]

gabapentin 100 mg capsule, 100

4591P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	15.52	6.50	^a APO-Gabapentin [TX] ^a Gabapentin Aspen 100 [RW] ^a Nupentin 100 [AF]	^a Gabapentin APOTEX [TY] ^a Neurontin [PF]

gabapentin 600 mg tablet, 100

4594T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	40.70	6.50	^a APO-Gabapentin [TX] ^a Gabapentin APOTEX [TY] ^a GenRx Gabapentin [GX]	^a Gabapentin AN [EA] ^a Gabapentin Aspen 600 [RW] ^a Neurontin [PF]

■ **PSYCHOLEPTICS****ANXIOLYTICS***Benzodiazepine derivatives*■ **BROMAZEPAM**

Note This drug should not be used as the first line of treatment.

Note Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

Note Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

Authority required

Terminal disease

Clinical criteria:

- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

Authority required

Refractory phobic or anxiety states

Clinical criteria:

- The treatment must be for the short-term.

bromazepam 3 mg tablet, 30

4150K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*31.55	6.50	Lexotan [RO]

bromazepam 6 mg tablet, 30

4151L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*37.29	6.50	Lexotan [RO]

Azaspirodecanedione derivatives■ **BUSPIRONE****Authority required**

Anxiety

Clinical criteria:

- The treatment must be for the short-term.

buspirone hydrochloride 10 mg tablet, 50

4145E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	55.40	6.50	Buspar [QA]

buspirone hydrochloride 5 mg tablet, 50

4144D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	38.93	6.50	Buspar [QA]

HYPNOTICS AND SEDATIVES*Benzodiazepine derivatives*■ **FLUNITRAZEPAM**

Note This drug should not be used as the first line of treatment.

Note Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

Note Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

Authority required

Terminal disease

Clinical criteria:

- The treatment must be for the short-term, **AND**
- Patient must be receiving palliative care.

Authority required

Refractory phobic or anxiety states

Clinical criteria:

- The treatment must be for the short-term.

flunitrazepam 1 mg tablet, 30

4216X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	19.59	6.50	Hypnodorm [AF]

Benzodiazepine related drugs

▪ **ZOPICLONE**

Restricted benefit

Insomnia

Clinical criteria:

- The treatment must be for the short-term.

zopiclone 7.5 mg tablet, 30

4522B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	24.82	6.50	^a APO-Zopiclone [TX]	^a Chem mart Zopiclone [CH]
						^a Imoclone [RW]	^a Imrest [AF]
						^a Terry White Chemists Zopiclone [TW]	^a Zopiclone GH [GQ]
			..	27.56	6.50	^a Imovane [SW]	

▪ **OTHER NERVOUS SYSTEM DRUGS**

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in nicotine dependence

▪ **NICOTINE**

Note Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.

Authority required

Nicotine dependence

Clinical criteria:

- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must have entered a comprehensive support and counselling program.

nicotine 21 mg/24 hours patch, 7

4573Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*58.09	6.50	QuitX [AF]
			..	*68.15	6.50	Nicabate CQ 21 [GC]

nicotine 7 mg/24 hours patch, 7

4571N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*51.97	6.50	QuitX [AF]

nicotine 14 mg/24 hours patch, 7

4572P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*55.13	6.50	QuitX [AF]
			..	*68.15	6.50	Nicabate CQ 14 [GC]

▪ **ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS**

▪ **ANTHELMINTICS**

ANTINEMATODAL AGENTS

Benzimidazole derivatives

▪ **MEBENDAZOLE**

mebendazole 100 mg tablet, 6

4325P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	17.68	6.50	Pharmacy Action Worm Treatment [GQ]

RESPIRATORY SYSTEM

NASAL PREPARATIONS

DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

Sympathomimetics, plain

OXYMETAZOLINE

oxymetazoline hydrochloride 0.05% nasal spray, 20 mL

11711J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	20.47	6.50	Pharmacy Action Nasal Decongestant [GQ]

oxymetazoline hydrochloride 0.05% nasal spray, 18 mL

4379L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	20.47	6.50	Logicin Rapid Relief [QA]

oxymetazoline hydrochloride 0.05% nasal spray, 15 mL

4378K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	20.81	6.50	Drixine [BN]

Antiallergic agents, excl. corticosteroids

CROMOGLYCATE

sodium cromoglycate 2% nasal spray, 26 mL

4468E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	25.82	6.50	Rynacrom [SW]

Corticosteroids

BUDESONIDE

Restricted benefit

Severe intractable rhinitis

budesonide 64 microgram/actuation nasal spray, 120 actuations

4092J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	42.07	6.50	Budamax Aqueous [JT]

Other nasal preparations

IPRATROPIUM

Restricted benefit

Severe intractable rhinorrhoea

Clinical criteria:

- The condition must be associated with perennial rhinitis, **AND**
- The condition must be unresponsive to insufflated nasal steroids.

ipratropium bromide monohydrate 44 microgram/actuation nasal spray, 180 actuations

4090G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	33.02	6.50	Atrovent Nasal Forte [VZ]

ipratropium bromide monohydrate 22 microgram/actuation nasal spray, 180 actuations

4089F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	26.87	6.50	Atrovent Nasal Aqueous [VZ]

NASAL DECONGESTANTS FOR SYSTEMIC USE

Sympathomimetics

PSEUDOEPHEDRINE

pseudoephedrine hydrochloride 60 mg tablet, 12

4029C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	14.83	6.50	^a Pharmacy Action Sinus & Nasal Decongestant Relief [GQ]
			..	15.48	6.50	^a Logicin Sinus [QA]

COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Expectorants

■ AMMONIUM + SENEGA ROOT

ammonium bicarbonate 25 mg/mL + senega root 25 mg/mL oral liquid, 200 mL

4074K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	4	..	13.88	6.50	Gold Cross [BI]

COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

Opium alkaloids and derivatives

■ PHOLCODINE

pholcodine 1 mg/mL oral liquid, 100 mL

4071G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	13.74	6.50	Gold Cross [BI]

■ ANTIHISTAMINES FOR SYSTEMIC USE

ANTIHISTAMINES FOR SYSTEMIC USE

Piperazine derivatives

■ CETIRIZINE

cetirizine hydrochloride 10 mg tablet, 30

4175R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	28.45	6.50	^a Pharmacy Action Cetrelief [GQ]
			..	31.68	6.50	^a Alzene [AF]
			..	34.48	6.50	Zilarex [SZ]

Other antihistamines for systemic use

■ FEXOFENADINE

fexofenadine hydrochloride 120 mg tablet, 30

4238C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	28.27	6.50	^a Pharmacy Action Fexorelief 120 [GQ]
			..	31.48	6.50	^a Xergic [AF]
			..	47.69	6.50	^a Telfast 120 [SW]

fexofenadine hydrochloride 60 mg tablet, 20

4237B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*55.54	6.50	Telfast [SW]

■ LORATADINE

loratadine 10 mg tablet, 30

4313B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	30.88	6.50	^a Pharmacy Action Lorastyne [GQ]
			..	34.58	6.50	^a Allereze [AF]
			..	44.21	6.50	^a Lorano [SZ]
			..	46.48	6.50	^a Claratyne [BN]

■ SENSORY ORGANS

■ OTOLOGICALS

OTHER OTOLOGICALS

Indifferent preparations

■ CARBAMIDE PEROXIDE

carbamide peroxide 6.5% ear drops, 12 mL

4176T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.96	6.50	Ear Clear for Ear Wax Removal [KY]

■ DOCUSATE

docusate sodium 0.5% ear drops, 10 mL

4199B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.48	6.50	Waxsol [GO]

- **ORTHO-DICHLOROBENZENE + PARA-DICHLOROBENZENE + CHLOROBUTANOL + ARACHIS OIL**
ortho-dichlorobenzene 14% + para-dichlorobenzene 2% + chlorobutanol hemihydrate 5% + arachis oil 57% ear drops, 10 mL

4180B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	18.14	6.50	Cerumol [UN]

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Drugs for treatment of hyperkalemia and hyperphosphatemia

SODIUM POLYSTYRENE SULFONATE

sodium polystyrene sulfonate 999.3 mg/g powder, 454 g

4470G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	70.30	6.50	Resonium-A [SW]

GENERAL NUTRIENTS

OTHER NUTRIENTS

Other combinations of nutrients

PROTEIN FORMULA WITH ARGININE, VITAMIN C AND E

Restricted benefit

Stage 2 and above pressure injury

Clinical criteria:

- The treatment must be for special medical purposes to support healing of pressure injuries.

protein formula with arginine, vitamin C and E powder for oral liquid, 14 x 9.2 g sachets

10850C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*158.99	6.50	Arginaid [NT]

PROTEIN FORMULA WITH ARGININE, VITAMIN C, E AND ZINC

Restricted benefit

Stage 2 and above pressure injury

Clinical criteria:

- The treatment must be for special medical purposes to support healing of pressure injuries.

protein formula with arginine, vitamin C, E and zinc oral liquid, 27 x 237 mL cartons

10841N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*263.57	6.50	Arginaid Extra [NT]

protein formula with arginine, vitamin C, E and zinc oral liquid, 24 x 200 mL bottles

11401C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*201.21	6.50	Cubitan [SB]

ALL OTHER NON-THERAPEUTIC PRODUCTS

ALL OTHER NON-THERAPEUTIC PRODUCTS

LUBRICATING AGENT

lubricating agent gel, 100 g

4306P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	14.71	6.50	Lubri-Gel [PP]

Other non-therapeutic auxiliary products

BANDAGE ABSORBENT WOOL

bandage absorbent wool 10 cm x 3 m bandage, 1

4653X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	23.57	6.50	Surepress 650948 [CC]

■ BANDAGE CALICO

bandage calico large triangular bandage, 1

4717G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	17.49	6.50	Handy 36361414 [BV]

■ BANDAGE COMPRESSION

bandage compression 10 cm x 3.5 m soft bandage [1] (&) bandage compression 10 cm x 6 m short stretch bandage [1], 1 pack

11714M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	38.07	6.50	Rosidal TCS 26484 [LC]

■ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

bandage compression 10 cm x 3 m high stretch bandage, 1

4748X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*71.94	6.50	Surepress 650947 [CC]
			..	*150.24	6.50	Tensopress 71723-00 [BV]

bandage compression 8 cm x 2.6 m short stretch bandage, 1

4654Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*77.29	6.50	Comprilan 01027-00 [BV]

■ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

bandage compression four layer bandage, 1

4598B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*176.54	6.50	Profore Lite 66050415 [SN]

bandage compression four layer bandage, 1

4658E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*263.84	6.50	Profore 66050016 [SN]

■ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

bandage compression 10 cm x 3.5 m high stretch bandage, 1

4657D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*77.09	6.50	Setopress 3505 [MH]

■ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

Restricted benefit

Venous ulcer

Treatment Phase: Initial treatment

Restricted benefit

Venous ulcer

Treatment Phase: Continuing treatment

bandage compression two layer bandage, 1

4050E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	43.24	6.50	Coban 2 [MM]

■ **BANDAGE RETENTION COHESIVE HEAVY****bandage retention cohesive heavy 10 cm x 2 m bandage, 1**

4660G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*22.75	6.50	Coban 1584 [MM]

bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1

4814J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*30.41	6.50	Peg 7425 [MM]

bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1

4811F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*18.09	6.50	Peg 7420 [MM]

bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1

4813H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*24.23	6.50	Peg 7423 [MM]

bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1

4812G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*20.95	6.50	Peg 7422 [MM]

■ **BANDAGE RETENTION COHESIVE LIGHT****bandage retention cohesive light 2.5 cm x 2 m bandage, 2**

4718H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	17.62	6.50	Handygauze Cohesive 8631 [BV]

bandage retention cohesive light 6 cm x 2 m bandage, 1

4719J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*20.01	6.50	Handygauze Cohesive 8633 [BV]

bandage retention cohesive light 10 cm x 2 m bandage, 1

4662J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*33.87	6.50	Handygauze Cohesive 8635 [BV]

■ **BANDAGE RETENTION COTTON CREPE****bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1**

4728W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*25.23	6.50	Telfa 8253F [KE]
			..	*28.27	6.50	Tensocrepe 36307501 [BV]

bandage retention cotton crepe 10 cm x 2.3 m bandage, 1

4729X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*27.97	6.50	Telfa 8254F [KE]
			..	*33.41	6.50	Tensocrepe 36301001 [BV]

bandage retention cotton crepe 5 cm x 2.3 m bandage, 1

4727T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*21.05	6.50	Telfa 8252F [KE]
			..	*23.71	6.50	Tensocrepe 36300501 [BV]

■ **BANDAGE TUBULAR****bandage tubular size D (25 cm to 43 cm) straight bandage, 1**

4664L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	19.28	6.50	Elastoplast 2226 [BE]

bandage tubular size E (35 cm to 45 cm) straight bandage, 1

4665M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	19.28	6.50	Elastoplast 2227 [BE]

bandage tubular size C (15 cm to 25 cm) straight bandage, 1

4663K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	19.28	6.50	Elastoplast 2225 [BE]

■ BANDAGE TUBULAR

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bandage tubular 10 cm x 1 m bandage, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4859R	‡1	..	..	18.92	6.50	Tubigrip F 1548 [MH]

bandage tubular 7.5 cm x 1 m bandage, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4857P	‡1	..	..	18.92	6.50	Tubigrip D 1546 [MH]

bandage tubular 6.25 cm x 1 m bandage, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4855M	‡1	..	..	18.92	6.50	Tubigrip B 1520 [MH]

bandage tubular 6.75 cm x 1 m bandage, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4856N	‡1	..	..	18.92	6.50	Tubigrip C 1545 [MH]

bandage tubular 8.75 cm x 1 m bandage, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4858Q	‡1	..	..	18.92	6.50	Tubigrip E 1547 [MH]

■ BANDAGE TUBULAR FINGER

BANDAGE-TUBULAR (FINGER) Complete pack including applicator, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4798M	‡1	..	..	21.35	6.50	Tubegauz 0501633 [SS]

■ BANDAGE TUBULAR LIGHT WEIGHT

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

bandage tubular light weight 10 m large limb size bandage, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4673Y	‡1	..	..	30.36	6.50	Tubifast 2438 [MH]

bandage tubular light weight 10 m medium limb size bandage, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4672X	‡1	..	..	29.13	6.50	Tubifast 2436 [MH]

bandage tubular light weight 10 m small limb size bandage, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4671W	‡1	..	..	25.69	6.50	Tubifast 2434 [MH]

■ BANDAGE TUBULAR LONG STOCKING

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bandage tubular long stocking medium size bandage, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4797L	2	..	..	*38.19	6.50	Tubigrip 1483 [MH]

bandage tubular long stocking large size bandage, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4799N	2	..	..	*38.19	6.50	Tubigrip 1484 [MH]

bandage tubular long stocking small size bandage, 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4674B	2	..	..	*38.19	6.50	Tubigrip 1482 [MH]

bandage tubular long stocking XX/large size bandage, 1

4675C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*38.21	6.50	Tubigrip 1486 [MH]

■ BANDAGE TUBULAR SHORT STOCKING

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

bandage tubular short stocking large D/E size bandage, 1

4816L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*27.97	6.50	Tubigrip 1481 [MH]

bandage tubular short stocking medium C/D size bandage, 1

4815K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*27.97	6.50	Tubigrip 1480 [MH]

bandage tubular short stocking small B/C size bandage, 1

4661H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*27.97	6.50	Tubigrip 1479 [MH]

■ BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

bandage zinc paste 10 cm x 9.1 m bandage, 1

4670T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*30.93	6.50	Flexidress 650941 [CC]

■ BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

bandage zinc paste 7.5 cm x 6 m bandage, 1

4669R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*31.69	6.50	Steripaste 3610 [MH]

■ BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

bandage zinc paste 7.5 cm x 6 m bandage, 1

4750B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*89.57	6.50	Viscopaste 4948 [SN]

bandage zinc paste 80 cm (stockings) bandage, 4

4760M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	102.65	6.50	ZipZoc 66000747 [SN]

■ BETAINE + POLYAMINOPROPYL BIGUANIDE**betaine 0.1% + polyaminopropyl biguanide 0.1% solution, 6 x 40 mL ampoules**

2525X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	29.09	6.50	Prontosan Wound Irrigation Solution [BR]

■ CADEXOMER-IODINE

Note Suitable for yellow sloughy infected and malodorous wounds.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

cadexomer-iodine 50% ointment, 2 x 20 g

4933P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	125.69	6.50	Iodosorb Ointment 66051230 [SN]

cadexomer-iodine 3 g powder, 7 sachets

4931M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	80.30	6.50	Iodosorb Powder 66051070 [SN]

cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheet

4936T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	171.76	6.50	Iodosorb 66051340 [SN]

cadexomer-iodine 6 cm x 4 cm dressing, 5 x 5 g sheet

4935R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	120.09	6.50	Iodosorb 66051330 [SN]

cadexomer-iodine 10 cm x 8 cm dressing, 2 x 17 g sheet

4937W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	180.77	6.50	Iodosorb 66051360 [SN]

cadexomer-iodine 50% ointment, 4 x 10 g

4932N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	126.84	6.50	Iodosorb Ointment 66051240 [SN]

▪ DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND**dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10**

4742N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	77.44	6.50	CarboFLEX 403202 [CC]

dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1

4681J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*97.39	6.50	Actisorb Plus MAP105 [KI]

dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5

4743P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	87.34	6.50	CarboFLEX 403204 [CC]

▪ DRESSING ALGINATE CAVITY WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

dressing alginate cavity wound 2 g rope, 5 x 2 g

1905G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*110.43	6.50	Kaltostat 168117 [CC]

dressing alginate cavity wound 2 g rope, 1

4832H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*104.89	6.50	Sorbsan 1411 [UM]

▪ DRESSING ALGINATE CAVITY WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g

4682K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*130.85	6.50	Comfeel SeaSorb Filler 3740 [CT]

▪ DRESSING ALGINATE SUPERFICIAL WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

dressing alginate superficial wound 7.5 cm x 12 cm dressing, 10

4683L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	88.44	6.50	Kaltostat 168212 [CC]

■ DRESSING ALGINATE SUPERFICIAL WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing alginate superficial wound 5 cm x 5 cm dressing, 10

4699H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	49.96	6.50	Kaltostat 168210 [CC]
			..	62.87	6.50	Algisite M 66000519 [SN]

dressing alginate superficial wound 15 cm x 20 cm dressing, 10

4691X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	284.11	6.50	Algisite M 66000521 [SN]

dressing alginate superficial wound 10 cm x 10 cm dressing, 10

4700J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	117.98	6.50	Algisite M 66000520 [SN]

■ DRESSING ALGINATE SUPERFICIAL WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing alginate superficial wound 5 cm x 5 cm dressing, 1

4684M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*47.49	6.50	Comfeel SeaSorb Dressing 3705 [CT]

dressing alginate superficial wound 10 cm x 10 cm dressing, 1

4831G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*82.39	6.50	Sorbsan 1410 [UM]
			..	*87.59	6.50	Comfeel SeaSorb Dressing 3710 [CT]

■ DRESSING ALGINATE WITH MANUKA HONEY

Note Suitable for yellow sloughy infected and malodorous wounds.

dressing alginate with manuka honey 10 cm x 10 cm dressing, 5

10849B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	4	..	63.95	6.50	Algivon Plus CR4225 [DJ]

dressing alginate with manuka honey 2.5 cm x 20 cm ribbon, 5

10857K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	4	..	115.24	6.50	Algivon Plus Ribbon & Probe CR4231 [DJ]

■ DRESSING FILM**dressing film 10 cm x 12 cm dressing, 4**

4687Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	22.98	6.50	Nexcare Tegaderm Transparent H1626 [MM]

dressing film 15 cm x 20 cm dressing, 1

4688R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	..	..	*32.53	6.50	Tegaderm Transparent 1628 [MM]

dressing film 6 cm x 7 cm dressing, 8

4686P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	19.50	6.50	Nexcare Tegaderm Transparent H1624 [MM]

▪ DRESSING FILM

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dressings film 10 cm x 12 cm dressing, 10

4893M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	39.87	6.50	Op-Site Flexigrid 4629 [SN]

▪ DRESSING FILM ISLAND

dressings film island 5 cm x 7 cm dressing, 1

4689T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*19.99	6.50	Tegaderm Transparent Island 3582 [MM]

dressings film island 9 cm x 10 cm dressing, 1

4690W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*29.99	6.50	Tegaderm Transparent Island 3586 [MM]

▪ DRESSING FILM ISLAND

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dressings film island 8 cm x 10 cm dressing, 5

4899W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*49.99	6.50	Cutifilm Plus 36361371 [SN]

dressings film island 5 cm x 7.2 cm dressing, 5

4898T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*33.27	6.50	Cutifilm Plus 36361370 [SN]

▪ DRESSING FOAM HEAVY EXUDATE

Note This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

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dressings foam heavy exudate 10 cm x 10 cm dressing, 10

4795J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	147.27	6.50	Allevyn 66007637 [SN]

▪ DRESSING FOAM MODERATE EXUDATE

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dressings foam moderate exudate cavity conforming foam, 20 g sachet

4694C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	99.31	6.50	Cavicare 4563 [SN]

▪ DRESSING FOAM MODERATE EXUDATE

Note This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

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dressings foam moderate exudate 12.5 cm x 12.5 cm dressing, 10

4590N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	146.70	6.50	Allevyn Adhesive 66000044 [SN]

■ DRESSING FOAM WITH SILICONE

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10029W dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	88.53	6.50	Allevyn Life 66801068 [SN]

10023M dressing foam with silicone 15.4 cm x 15.4 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	121.29	6.50	Allevyn Life 66801069 [SN]

10021K dressing foam with silicone 21 cm x 21 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	241.18	6.50	Allevyn Life 66801070 [SN]

10017F dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	62.83	6.50	Allevyn Life 66801067 [SN]

11384E dressing foam with silicone 10.5 cm x 10.5 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	62.83	6.50	Allevyn Life Non-Bordered 66801748 [SN]

11393P dressing foam with silicone 16 cm x 16 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	107.38	6.50	Allevyn Life Non-Bordered 66801749 [SN]

■ DRESSING FOAM WITH SILICONE AND SILVER

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

Authority required

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

2439J dressing foam with silicone and silver 10 cm x 10 cm dressing, 5

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	105.01	6.50	Mepilex Ag [MH]

2470B dressing foam with silicone and silver 10 cm x 10 cm dressing, 5

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	112.06	6.50	Mepilex Border Ag [MH]

■ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

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4196W dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	83.48	6.50	Allevyn Gentle 66800248 [SN]

4230P dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	83.48	6.50	Allevyn Gentle Border 66800270 [SN]

4207K dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
‡1	..	..	59.48	6.50	Allevyn Gentle Border 66800269 [SN]

▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

Note Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

dressings foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 5

4642H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	32.65	6.50	Mepilex Border 295200 [MH]

dressings foam with silicone heavy exudate 10 cm x 10 cm dressing, 5

4643J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	43.24	6.50	Mepilex Border 295300 [MH]

▪ DRESSING FOAM WITH SILICONE LIGHT EXUDATE

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dressings foam with silicone light exudate 10 cm x 10 cm dressing, 5

4645L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	39.12	6.50	Mepilex Lite 284100 [MH]

dressings foam with silicone light exudate 6 cm x 8.5 cm dressing, 5

4644K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	30.30	6.50	Mepilex Lite 284000 [MH]

▪ DRESSING FOAM WITH SILICONE MODERATE EXUDATE

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dressings foam with silicone moderate exudate 10 cm x 10 cm dressing, 5

4626L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	43.24	6.50	Mepilex 294100 [MH]

▪ DRESSING FOAM WITH SILVER

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

Authority required

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressings foam with silver 7.5 cm x 7.5 cm dressing, 10

4252T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	150.82	6.50	Allevyn Ag Adhesive 66800073 [SN]

dressings foam with silver 7.5 cm x 7.5 cm dressing, 10

4263J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	150.82	6.50	Allevyn Ag Gentle Border 66800460 [SN]

dressings foam with silver 10 cm x 10 cm dressing, 10

4255Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	223.11	6.50	Allevyn Ag Adhesive 66800075 [SN]

dressings foam with silver 10 cm x 10 cm dressing, 10

4259E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	227.44	6.50	Allevyn Ag Non-Adhesive 66800086 [SN]

dressing foam with silver 10 cm x 10 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4266M	‡1	..	..	223.11	6.50	Allevyn Ag Gentle Border 66800461 [SN]

dressing foam with silver 12.5 cm x 12.5 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4258D	‡1	..	..	277.61	6.50	Allevyn Ag Adhesive 66800078 [SN]

dressing foam with silver 12.5 cm x 12.5 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4270R	‡1	..	..	277.61	6.50	Allevyn Ag Gentle Border 66800462 [SN]

▪ DRESSING GAUZE**dressing gauze eye pad, 12 pads**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4768Y	‡1	..	..	17.05	6.50	Curity 4112 [KE]

▪ DRESSING GAUZE ABSORBENT**dressing gauze absorbent 5 cm x 5 cm pad, 100**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4707R	‡1	..	..	19.08	6.50	Handy 71117-05 [BV]

dressing gauze absorbent 10 cm x 10 cm pad, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4708T	‡1	..	..	32.81	6.50	Handy 71117-06 [BV]

▪ DRESSING GAUZE PARAFFIN

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing gauze paraffin 10 cm x 10 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4759L	‡1	..	..	26.44	6.50	Jelonet 7404 [SN]

▪ DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4845B	‡1	2	..	33.73	6.50	Bactigras 7457 [SN]

▪ DRESSING HYDROACTIVE DEBRIDEMENT

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

dressing hydroactive debridement 7.5 cm x 7.5 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4950M	‡1	..	..	110.41	6.50	TenderWet 24 Active 609213 [HR]

dressing hydroactive debridement 5.5 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4948K	‡1	..	..	84.67	6.50	TenderWet Active Cavity 609272 [HR]

dressing hydroactive debridement 4 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4949L	‡1	..	..	82.81	6.50	TenderWet 24 Active 609210 [HR]

■ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings

4695D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	106.77	6.50	Tielle MTL101E [KI]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm (foam alternative) dressing, 10

4692Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	55.46	6.50	CombiDERM 651031 [CC]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing: island, 5 dressings

4696E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	129.13	6.50	Tielle MTL103 [KI]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 18 cm (foam alternative) dressing, 5

4693B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	70.84	6.50	CombiDERM 651027 [CC]

■ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm waterproof pad, 5

4930L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	90.93	6.50	Biatain Adhesive 3423 [CT]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm waterproof pad, 5

4928J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	84.23	6.50	Biatain Non-adhesive 3413 [CT]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm waterproof pad, 10

4927H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	85.58	6.50	Biatain Non-adhesive 3410 [CT]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm waterproof pad, 10

4929K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	93.78	6.50	Biatain Adhesive 3420 [CT]

■ DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE

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dressing hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10

4905E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	71.07	6.50	Allevyn Thin 66047576 [SN]

dressing hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5

4906F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*126.63	6.50	Allevyn Thin 66047578 [SN]

■ DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE

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cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing hydroactive superficial wound moderate exudate 10 cm x 10 cm dressing, 5

4886E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*96.01	6.50	Cutinova Hydro 66047443 [SN]

dressing hydroactive superficial wound moderate exudate 5 cm x 6 cm dressing, 10

4885D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	58.56	6.50	Cutinova Hydro 66047441 [SN]

▪ DRESSING HYDROCOLLOID CAVITY WOUND

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

dressing hydrocolloid cavity wound paste, 30 g

4896Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*137.59	6.50	DuoDERM Paste 187930 [CC]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

Note This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

4907G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	70.84	6.50	DuoDERM Extra Thin 187955 [CC]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

Note This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing hydrocolloid superficial wound light exudate 9 cm x 14 cm dressing, 10

4889H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	82.48	6.50	Comfeel Plus Transparent 3536 [CT]

dressing hydrocolloid superficial wound light exudate 5 cm x 7 cm dressing, 10

4888G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	42.28	6.50	Comfeel Plus Transparent 3530 [CT]

dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

4924E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	69.08	6.50	Comfeel Plus Transparent 3533 [CT]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

Note This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

4947J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	48.71	6.50	Hydrocoll Thin 900758 [HR]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5

4897R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*79.65	6.50	DuoDERM CGF 187660 [CC]

dressings hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5

4920Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*210.01	6.50	DuoDERM CGF 187662 [CC]

■ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

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dressings hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10

4921B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	97.00	6.50	Repicare Ultra 66000434 [SN]

■ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

dressings hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10

4945G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	48.71	6.50	Hydrocoll 900744 [HR]

dressings hydrocolloid superficial wound moderate exudate 15 cm x 15 cm dressing, 10

4946H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	87.38	6.50	Hydrocoll 900936 [HR]

■ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

DRESSING-HYDROCOLLOID (SUPERFICIAL WOUND-MODERATE EXUDATE) Dressings with alginate 10 cm x 10 cm, 10, 1

4923D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	80.19	6.50	Comfeel Plus Ulcer Dressing 3110 [CT]

dressings hydrocolloid superficial wound moderate exudate 10cm (round) dressing, 1

4679G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*59.84	6.50	Comfeel Plus Pressure Relieving 3353 [CT]

dressings hydrocolloid superficial wound moderate exudate 7cm (butterfly shape) dressing, 1

4678F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*55.74	6.50	Comfeel Plus Pressure Relieving 3350 [CT]

■ DRESSING HYDROFIBRE ALTERNATE TO ALGINATES**dressings hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5**

2803M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*195.91	6.50	Aquacel Extra 420673 [CC]

dressings hydrofibre alternate to alginates 2 g (30 cm) rope, 5 x 2 g

4698G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	81.74	6.50	Aquacel 403770 [CC]

dressings hydrofibre alternate to alginates 12.5 cm x 12.5 cm dressing, 10

10832D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	117.12	6.50	Aquacel Foam Adhesive [CC]

dressings hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10

10837J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	120.59	6.50	Aquacel Foam Non-Adhesive [CC]

dressings hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10

2797F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	97.44	6.50	Aquacel Extra 420672 [CC]

■ DRESSING HYDROFIBRE GELLING FIBRE

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dressings hydrofibre gelling fibre 10 cm x 10 cm dressing, 10

2486W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	107.55	6.50	Durafiber 66800560 [SN]

dressings hydrofibre gelling fibre 15 cm x 15 cm dressing, 5

2445Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*219.85	6.50	Durafiber 66800561 [SN]

dressings hydrofibre gelling fibre 2 cm x 45 cm rope, 5

2462N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	92.69	6.50	Durafiber 66800563 [SN]

■ DRESSING HYDROFIBRE WITH SILVER**Authority required**

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressings hydrofibre with silver 10 cm x 10 cm dressing, 10

10097K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	251.14	6.50	Aquacel Ag 403708 [CC]

dressings hydrofibre with silver 15 cm x 15 cm dressing, 5

10098L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	268.78	6.50	Aquacel Ag 403710 [CC]

dressings hydrofibre with silver 2 cm x 45 cm rope, 5

10105W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	212.20	6.50	Aquacel Ag 403771 [CC]

■ DRESSING HYDROGEL**dressings hydrogel 10 cm x 10 cm dressing, 5**

11709G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	30.03	6.50	Suprasorb G 33631 [LC]

dressings hydrogel 10 cm x 10 cm dressing, 20

2471C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	121.53	6.50	Sorbact Absorption Dressing S98222 [YB]

dressings hydrogel 7.5 cm x 15 cm dressing, 10

11395R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	78.30	6.50	Sorbact Gel Dressing S98137 [YB]

■ DRESSING HYDROGEL AMORPHOUS

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

dressings hydrogel amorphous gel, 3 x 30 g

4913N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*93.91	6.50	DuoDERM Gel H7987 [CC]

dressings hydrogel amorphous gel, 50 g

4914P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*34.69	6.50	Solugel 10336 [JJ]

■ DRESSING HYDROGEL AMORPHOUS

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

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dressing hydrogel amorphous gel, 10 x 15 g

4912M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	64.26	6.50	DuoDERM Gel 187990 [CC]
			..	71.18	6.50	Comfeel Purilon Gel 3900 [CT]

■ DRESSING HYDROGEL AMORPHOUS

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

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dressing hydrogel amorphous gel, 50 g

4599C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*36.97	6.50	SoloSite Gel 36361338 [SN]

dressing hydrogel amorphous gel, 25 g

4894N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*76.11	6.50	Intrasite Gel 7313 [SN]

■ DRESSING HYDROGEL FOAM

dressing hydrogel foam 10 cm x 10 cm dressing, 10

2533H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	86.15	6.50	Sorbact Foam Dressing S98310 [YB]

■ DRESSING HYDROGEL RIBBON

dressing hydrogel ribbon 5 cm x 200 cm dressing, 10

2529D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	121.53	6.50	Sorbact Ribbon Gauze S98120 [YB]

dressing hydrogel ribbon 1 cm x 50 cm dressing, 20

2512F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	125.45	6.50	Sorbact Ribbon Gauze S98118 [YB]

■ DRESSING HYDROGEL SHEET

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5

4911L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*81.29	6.50	Nu-Gel 2497 [KI]

■ DRESSING HYDROGEL SHEET

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

dressing hydrogel sheet 10 cm x 10 cm dressing, 5

4806Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*53.85	6.50	Hydrosorb 900854 [HR]

■ DRESSING HYDROPHOBIC

dressings hydrophobic 15 cm x 15 cm dressing, 10

11394Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	199.20	6.50	Sorbact Foam Gentle Border 98533 [YB]

dressings hydrophobic 10 cm x 10 cm dressing, 10

11392N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	126.37	6.50	Sorbact Foam Gentle Border 98532 [YB]

dressings hydrophobic 10 cm x 10 cm dressing, 10

11402D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	62.28	6.50	Sorbact Superabsorbent 98501 [YB]

dressings hydrophobic 20 cm x 20 cm dressing, 10

11403E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	150.56	6.50	Sorbact Superabsorbent 98503 [YB]

dressings hydrophobic 15 cm x 15 cm foam dressing, 10

11404F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	133.30	6.50	Sorbact Foam Dressing S98315 [YB]

■ DRESSING NON ADHERENT

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DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 7.5 cm x 10 cm, 10, 1

4244J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	103.48	6.50	Mepitel 290710 [MH]

DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10, 1

4243H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	63.48	6.50	Mepitel 290510 [MH]

■ DRESSING NON ADHERENT

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dressings non adherent 7.5 cm x 10 cm dressing, 10

4944F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	19.15	6.50	Atrauman 499513 [HR]

■ DRESSING NON ADHERENT

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dressings non adherent 5 cm x 5 cm dressing, 5

4819P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*20.37	6.50	Cutilin Non-Stick Wound Pad 36361374 [SN]

dressings non adherent 5 cm x 5 cm dressing, 5

4860T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*21.73	6.50	Melolin 36361357 [SN]

dressings non adherent 10 cm x 10 cm dressing, 10

4861W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	39.88	6.50	Melolin 66974933 [SN]

dressings non adherent 10 cm x 10 cm dressing, 5

4862X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*29.51	6.50	Cutilin Non-Stick Wound Pad 36361375 [SN]

■ DRESSING NON-ADHERENT ABSORBENT**dressings non-adherent absorbent 22 cm x 32 cm hydroactive dressing, 10**

11718R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	49.11	6.50	Vliwasorb Pro 32644 [LC]

dressings non-adherent absorbent 22 cm x 22 cm hydroactive dressing, 10

11715N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	36.53	6.50	Vliwasorb Pro 32643 [LC]

dressings non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 10

11717Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	25.67	6.50	Vliwasorb Pro 32641 [LC]

■ DRESSING TULLE NON GAUZE PARAFFIN**dressings tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1**

4909J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*19.59	6.50	Adaptic 2012 [KI]

■ DRESSING WITH SILVER

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

Authority required

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressings with silver 10 cm x 10 cm hydroactive dressing, 5

4646M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	165.53	6.50	Biatain Ag 9622 [CT]

dressings with silver 12.5 cm x 12.5 cm hydroactive dressing, 5

4647N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	179.54	6.50	Biatain Ag 9632 [CT]

■ DRESSING WITH SILVER

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Authority required

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressings with silver 10 cm x 10 cm tulle dressing, 3

4648P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	44.34	6.50	Atrauman Ag 499572 [HR]

■ GAUZE AND COTTON TISSUE COMBINE ROLL**gauze and cotton tissue combine roll 9 cm x 10 m wrapped pack roll, 1**

4767X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	16.17	6.50	BSN 2902165 [BV]

gauze and cotton tissue combine roll 10 cm x 10 m wrapped pack roll, 1

4761N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.86	6.50	JJ 12010 [JJ]

■ PAD WOUND DEBRIDEMENT

Note If the wound has not healed during this period, further use is to be discontinued after initial pack, no repeats. Where wounds remain unresponsive to standard treatment, patient should be referred on to a specialist.

pad wound debridement pad, 5

11391M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	91.85	6.50	Debrisoft Lolly [LC]

pad wound debridement 10 cm x 10 cm pad, 5

11383D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	91.85	6.50	Debrisoft [LC]

■ POVIDONE-IODINE

povidone-iodine 9.5 cm x 9.5 cm dressing, 25

10847X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	78.03	6.50	Inadine [KI]

■ SODIUM CHLORIDE + HYPOCHLOROUS ACID + SODIUM HYPOCHLORITE

sodium chloride 0.022% + hypochlorous acid 0.004% + sodium hypochlorite 0.004% irrigation solution, 250 mL

11134B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	30.83	6.50	Microdacyn [TF]

■ TAPE NON WOVEN RETENTION POLYACRYLATE

tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll

4915Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	17.09	6.50	Medipore 2961 [MM]

■ TAPE NON WOVEN RETENTION POLYACRYLATE

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tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll

4917T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.50	6.50	Mefix 310250 [MH]

■ TAPE PLASTER ADHESIVE ELASTIC

tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll

4780N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.01	6.50	Leukoplast 01071-00 [BV]

tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll

4782Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	27.63	6.50	Leukoplast 01073-00 [BV]

tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll

4781P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	23.95	6.50	Leukoplast 01072-00 [BV]

■ TAPE PLASTER ADHESIVE HYPOALLERGENIC

tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll

4848E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.51	6.50	Nexcare Durable Cloth First Aid Tape 799 [MM]

tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll

4787Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	18.36	6.50	Leukosilk 1022 [BV]

tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll

4794H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	17.83	6.50	Leukopor 2472 [BV]

tape plaster adhesive hypoallergenic 1.9 cm x 7.3 m dispenser tape, 1 roll

4849F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.51	6.50	Nexcare Gentle Paper First Aid Tape 789 [MM]

tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll

4783R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.42	6.50	Leukopor 2471 [BV]

tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll

4785W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	15.71	6.50	Leukosilk 1021 [BV]

tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll

4788B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	20.86	6.50	Leukoflex 1124 [BV]

tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll

4789C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	22.18	6.50	Leukosilk 1024 [BV]

tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll

4790D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	21.35	6.50	Leukopor 2474 [BV]

■ TAPE PLASTER ADHESIVE WITH SILICONE

Note Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll

4239D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	24.48	6.50	Mepitac 298300 [MH]

tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll

4240E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	24.48	6.50	Mepitac 298400 [MH]

Extemporaneously Prepared Benefits

Drug Tariff

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Acacia Mucilage (by weight)	APF 15	0.01	0.11	0.88	7.79
Acacia, powdered	BP	0.03	0.20	1.58	14.02
Acetic Acid (33 per cent)	BP	0.01	0.06	0.47	4.14
Acetic Acid (6 per cent)	BP	0.01	0.02	0.16	1.40
Acetic Acid Glacial BP	BP	0.02	0.14	1.09	9.72
Acetone (use as additive only)	BP	0.02	0.19	1.49	13.22
Alum	BP	0.01	0.07	0.59	5.28
Aluminium Acetate Solution	BP	0.02	0.17	1.38	12.27
Anise Oil BP	BP	0.18	1.44	11.52	102.44
Anise Water Concentrated 1 in 40	BP	0.01	0.07	0.59	5.27
Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.05	0.39	3.44
Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures)	BP	0.38	3.00	24.00	213.30
Aspirin	BP	0.14	1.11	8.90	79.09
Belladonna Tincture	BP	0.18	1.45	11.59	103.06
Benzocaine	BP	0.13	1.06	8.50	75.59
Benzoic Acid	BP	0.07	0.52	4.13	36.69
Benzoic Acid Compound Ointment	APF	0.02	0.17	1.37	12.16
Benzoic Acid Solution	BP	0.02	0.14	1.09	9.69
Benzoin Compound Tincture	BP	0.06	0.51	4.04	35.92
Boric Acid (use as additive only)	BP	0.02	0.17	1.38	12.26
Boric Acid, Olive Oil and Zinc Oxide Ointment	QHF	0.02	0.14	1.13	10.06
Calcium Hydroxide	BP	0.11	0.86	6.85	60.85
Calcium Hydroxide Solution	BP	0.01	0.02	0.19	1.65
Castor Oil (use as additive only)	BP	0.02	0.17	1.37	12.14
Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.03	0.26	2.31
Cetrimide Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.02	0.17	1.37	12.21
Chlorhexidine Acetate (use as additive only)	BP	0.63	5.03	40.21	357.42
Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.03	0.24	1.95	17.36
Chloroform (use as additive only)	BP	0.09	0.72	5.77	51.32
Chloroform Spirit	BP	0.01	0.09	0.70	6.19
Chloroform Water Concentrated 1 in 40	APF 15	0.01	0.11	0.86	7.65
Citric Acid Monohydrate	BP	0.04	0.29	2.28	20.28
Coal Tar	BP	0.31	2.51	20.09	178.55
Coal Tar Solution	BP	0.02	0.19	1.48	13.17
Cocaine Hydrochloride	BP	6.03	48.22	385.72	3428.65
Coconut Oil	BP	0.01	0.06	0.48	4.24
Codeine Linctus	APF	0.02	0.13	1.00	8.88
Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)	BP	2.68	21.45	171.56	1524.99
Collodion Flexible	BP	0.19	1.55	12.37	109.96
Dithranol	BP	4.29	34.31	274.51	2440.09
Emulsifying Ointment (for use only as a base combined with active ingredients)	BP	0.01	0.07	0.57	5.11
Ephedrine Hydrochloride (may only be prescribed in nasal instillations)	BP	2.38	19.03	152.26	1353.39
Ethanol (90 per cent) (use as additive only)	BP	0.01	0.04	0.31	2.72
Ethanol (96 per cent) (use as additive only)	BP	0.01	0.05	0.39	3.47
Ether Solvent (use as additive only)	BP	0.27	2.15	17.18	152.70

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Eucalyptus Oil (use as additive only)	BP	0.03	0.20	1.62	14.42
Ferrous Sulfate	BP	0.05	0.37	2.94	26.12
Formaldehyde Solution	BP	0.07	0.53	4.26	37.86
Gentian Alkaline Mixture	APF	0.01	0.09	0.68	6.00
Glycerol	BP	0.02	0.12	0.99	8.78
Honey Purified (use as additive only)	BP 1993	0.01	0.03	0.27	2.44
Hydroxybenzoate Compound Solution	APF	0.09	0.68	5.40	47.98
Iodine	BP	0.33	2.61	20.86	185.45
Iodine Alcoholic Solution	BP	0.04	0.31	2.46	21.89
Iodine Aqueous Oral Solution	BP	0.04	0.30	2.41	21.45
Kaolin Mixture	BPC 1968	0.03	0.23	1.84	16.32
Kaolin and Opium Mixture	APF 14	0.01	0.10	0.82	7.27
Lactic Acid	BP	0.35	2.76	22.04	195.91
Lavender Spike Oil	BPC 1968	0.13	1.04	8.32	73.91
Liquorice Liquid Extract	BP	0.03	0.23	1.84	16.37
Magnesium Carbonate Light	BP	0.05	0.37	2.92	25.99
Magnesium Sulfate (may only be prescribed for other than oral use)	BP	0.01	0.03	0.27	2.37
Magnesium Trisilicate	BP	0.05	0.41	3.24	28.76
Menthol, Racemic or Levomenthol	BP	0.28	2.25	17.96	159.62
Methyl Hydroxybenzoate	BP	0.46	3.71	29.64	263.43
Methyl Hydroxybenzoate Solution	APF	0.05	0.38	3.00	26.70
Methylated Industrial Spirit (use as additive only)	BP	0.01	0.01	0.11	1.00
Olive Oil (use as additive only)	BP	0.02	0.13	1.01	9.00
Paraffin Hard	BP	0.06	0.45	3.57	31.74
Paraffin Light Liquid	BP	0.02	0.17	1.39	12.32
Paraffin Liquid (use as additive only)	BP	0.01	0.07	0.57	5.08
Paraffin Soft White	BP	0.01	0.06	0.47	4.18
Paraffin Soft Yellow	BP	0.01	0.05	0.42	3.75
Peppermint Oil (use as additive only)	BP	0.08	0.64	5.09	45.29
Peppermint Water Concentrated 1 in 40 (use as additive only)	APF 16	0.04	0.28	2.26	20.12
Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy)	BP	9.37	74.92	599.36	5327.61
Phenol Liquefied (not available for ear drops)	BP	0.24	1.90	15.17	134.83
Podophyllum Resin	BP	3.78	30.26	242.09	2151.88
Potassium Citrate	BP	0.03	0.21	1.66	14.78
Potassium Iodide	BP	0.16	1.24	9.91	88.09
Potassium Permanganate	BP	0.05	0.37	2.99	26.57
Propyl Hydroxybenzoate	BP	0.42	3.36	26.84	238.54
Propylene Glycol	BP	0.02	0.12	0.92	8.17
Red Syrup	APF 15	0.02	0.13	1.04	9.23
Resorcinol	BP	0.42	3.33	26.60	236.41
Salicylic Acid	BP	0.03	0.25	1.98	17.60
Salicylic Acid Ointment	APF	0.02	0.17	1.38	12.23
Salicylic Acid Ointment	BP	0.02	0.17	1.38	12.23
Simple Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.11	9.88
Simple Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.11	9.88
Sodium Bicarbonate	BP	0.02	0.19	1.49	13.25
Sodium Chloride	BP	0.02	0.18	1.46	13.02
Sodium Chloride Solution	BP	0.01	0.01	0.11	0.95
Sodium Citrate	BP	0.07	0.54	4.31	38.34
Sodium Thiosulfate (use as additive only)	BP	0.05	0.37	2.96	26.34
Starch	BP	0.02	0.12	0.95	8.45
Sulfur Ointment (for use only as a base combined with active ingredients)	BP 1980	0.02	0.15	1.22	10.89
Sulfur Precipitated	BP 1980	0.03	0.25	1.99	17.68
Syrup	BP	0.01	0.05	0.43	3.85
Talc Purified, sterilised	BP	0.06	0.48	3.81	33.83
Thymol	BP	0.51	4.11	32.84	291.88
Thymol Compound Mouth Wash	APF 15	0.02	0.13	1.00	8.89
Tragacanth Compound Powder	BP 1980	0.07	0.57	4.58	40.73
Tragacanth Mucilage	APF 13	0.01	0.08	0.66	5.87

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Tragacanth Mucilage	BPC 1973	0.01	0.07	0.59	5.20
Tragacanth, powdered	BP	0.41	3.27	26.15	232.44
Trichloroacetic Acid	BP 1980	0.38	3.04	24.29	215.91
Triethanolamine	BP	0.15	1.19	9.52	84.66
Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)	BP				
Water Purified	BP	0.01	0.01	0.09	0.79
Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.19	1.51	13.42
Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.19	1.48	13.18
Wool Fat	BP	0.02	0.18	1.44	12.79
Wool Fat Hydrous	BP	0.04	0.28	2.27	20.18
Zinc Compound Paste	BP	0.05	0.40	3.17	28.17
Zinc Cream (for use only as a base combined with active ingredients)	BP	0.01	0.09	0.73	6.49
Zinc Oxide	BP	0.03	0.21	1.71	15.22
Zinc Sulfate	BP	0.04	0.31	2.49	22.13
Zinc and Salicylic Acid Paste	BP	0.05	0.37	2.95	26.22

Container Prices

Type	Container	Price \$
Dispensing Bottles	25mL	0.66
Dispensing Bottles	50mL	0.70
Dispensing Bottles	100mL	0.82
Dispensing Bottles	200mL	1.00
Dispensing Bottles	500mL	1.28
Poison Bottles	25mL	0.72
Poison Bottles	50mL	0.73
Poison Bottles	100mL	0.79
Poison Bottles	200mL	1.08
Poison Bottles	500mL	1.97
Dropper Containers (Glass)	15mL	1.15
Dropper Containers (Polythene)	15mL	0.98
	150ml	1.00
Screw Cap Jars	25g	0.95
Screw Cap Jars	50g	1.01
Screw Cap Jars	100g	1.39
Screw Cap Jars	200g	0.77
Screw Cap Jars	500g	2.19
	25ml	0.51

Standard Formula Preparations

Code	Item	Reference	DPMQ \$	MRVSN \$
	Creams			
7502W	(Maximum Quantity 100 g and 1 Repeat) Salicylic Acid and Sulfur Aqueous	APF	15.12	16.73
	Dusting Powders			
7458M	(Maximum Quantity 100 g and 1 Repeat) Zinc, Starch and Talc	APF 15 & BPC 1973	35.89	37.50
	Ear Drops			
7643G	(Maximum Quantity 15 ml and 2 Repeats) Aluminium Acetate	BP	12.48	14.09
7642F	Aluminium Acetate	APF	11.72	13.33
7314Y	Sodium Bicarbonate	APF & BP	11.20	12.81
7313X	Spirit	APF	10.71	12.32
	Inhalations			
	(Maximum Quantity 50 ml and 1 Repeat)			
7484X	Benzoin and Menthol	APF	32.62	34.23
7308P	Menthol	APF	13.94	15.55
7310R	Menthol and Eucalyptus	BP1980	15.10	16.71
	Linctuses containing Codeine Phosphate			
	(Maximum Quantity 100 ml and 0 Repeat)			
7530H	Codeine	APF	19.13	20.74
	Lotions			
	(Maximum Quantity 200 ml and 2 Repeats)			
7709R	Aluminium Acetate Aqueous	APF	13.40	15.01
	Mixtures, Other			
	(Maximum Quantity 200 ml and 4 Repeats)			
7604F	Gentian Alkaline	APF	22.43	24.04
7348R	Kaolin	BPC 1968	43.07	40.30
7301G	Kaolin and Opium	APF 14	24.97	26.58
7342K	Magnesium Trisilicate	BPC 1968	21.04	22.65
7343L	Magnesium Trisilicate and Belladonna	BPC 1968	32.48	34.09
	Mouth Washes			
	(Maximum Quantity 200 ml and 1 Repeat)			
7457L	Thymol Compound	APF 15	28.29	29.90
	Ointments, Waxes			
	(Maximum Quantity 100 g and 1 Repeat)			
7914M	Benzoic Acid Compound	APF & BP	22.98	24.59
7902X	Boric Acid, Olive Oil and Zinc Oxide	QHF	20.88	22.49
7926E	Salicylic Acid	APF	23.05	24.66
7928G	Salicylic Acid (extemporaneous formula)	BP	23.05	24.66
	Paints			
	(Maximum Quantity 25 ml and 1 Repeat)			
7567G	Podophyllin Compound	APF 16 & BP	133.73	40.30
7568H	Salicylic Acid	APF	41.69	40.30
	Pastes, Other			
	(Maximum Quantity 100 g and 1 Repeat)			
7558T	Zinc	APF & BP	38.99	40.30
	Powders for Internal Use			
	(Maximum Quantity 100 g and 2 Repeats)			
7545D	Magnesium Trisilicate	BP	38.96	40.30

Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

Code	Preparation	Maximum Quantity	Number of Repeats
13Q	Creams	100 g	1
48M	Dusting Powders	100 g	1
15T	Ear Drops	15 ml	2
19B	Eye Drops containing Cocaine Hydrochloride	15 ml	..
22E	Eye Drops, Other	15 ml	5
23F	Eye Lotions	200 ml	2
29M	Inhalations	50 ml	1
64J	Linctuses containing Codeine Phosphate	100 ml	..
34T	Linctuses, Other	100 ml	2
39C	Lotions	200 ml	2
65K	Mixtures containing Codeine Phosphate	200 ml	..
66L	Mixtures for Children containing Codeine Phosphate	100 ml	..
41E	Mixtures for Children, Other	100 ml	4
40D	Mixtures, Other	200 ml	4
30N	Mouth Washes	200 ml	1
42F	Nasal Instillations	15 ml	2
43G	Ointments, Waxes	100 g	1
44H	Paints	25 ml	1
63H	Pastes containing Cocaine Hydrochloride	25 g	..
45J	Pastes, Other	100 g	1
49N	Powders for Internal Use	100 g	2
52R	Solutions	200 ml	2

Index of Manufacturers' Code

Code	Manufacturer	Code	Manufacturer
AB	Abbott Australasia Pty Ltd	GX	Apotex Pty Ltd
AE	AFT Pharmaceuticals (AU) Pty Ltd	GZ	sanofi-aventis Australia Pty Ltd
AF	Alphapharm Pty Ltd	HB	Besins Healthcare Australia Pty Ltd
AG	Allergan Australia Pty Limited	HN	Horizon Hospital Healthcare Pty Ltd
AL	Alphapharm Pty Ltd	HQ	Generic Health Pty Ltd
AN	Amgen Australia Pty Limited	HR	Paul Hartmann Pty Ltd
AP	AstraZeneca Pty Ltd	HX	Sandoz Pty Ltd
AQ	Alcon Laboratories (Australia) Pty Ltd	IB	Apotex Pty Ltd
AS	Aspen Pharmacare Australia Pty Limited	IG	Sigma Company Limited
AT	Actelion Pharmaceuticals Australia Pty Ltd	IJ	I-Care Pharma Distributors Pty Ltd
AV	sanofi-aventis Australia Pty Ltd	IL	iNova Pharmaceuticals (Australia) Pty Limited
BB	Blackmores Limited	IM	iNova Pharmaceuticals (Australia) Pty Limited
BD	Biogen Australia Pty Ltd	IO	BioMarin Pharmaceutical Australia Pty Ltd
BE	Beiersdorf Australia Ltd	IQ	Alcon Laboratories (Australia) Pty Ltd
BG	Sandoz Pty Ltd	IR	Indivior Pty Ltd
BI	Biotech Pharmaceuticals Pty Ltd	IS	Ipsen Pty Ltd
BN	Bayer Australia Ltd	IX	Clinect Pty Ltd
BQ	Bristol-Myers Squibb Australia Pty Ltd	IY	Clinect Pty Ltd
BR	B. Braun Australia Pty Ltd	JB	Apotex Pty Ltd
BV	BSN medical (Aust.) Pty Ltd	JC	Janssen-Cilag Pty Ltd
BX	Baxter Healthcare Pty Limited	JJ	Johnson & Johnson Medical Pty Ltd
BY	Boehringer Ingelheim Pty Ltd	JO	Juno Pharmaceuticals Pty Ltd
BZ	Boucher & Muir Pty Ltd	JT	Johnson & Johnson Pacific Pty Limited
CC	ConvaTec A Division of Bristol-Myers Squibb Australia Pty Ltd	JU	Juno Pharmaceuticals Pty Ltd
CF	CNS Pharma Pty Ltd	JX	Juno Pharmaceuticals Pty Ltd
CH	Apotex Pty Ltd	KE	Kendall Australasia Pty Ltd
CJ	Celgene Pty Limited	KI	KCI Medical Australia Pty Ltd
CR	Pharmacor Pty Limited	KP	Eli Lilly Australia Pty Ltd
CS	Seqirus (Australia) Pty Ltd	KY	Key Pharmaceuticals Pty Ltd
CT	Coloplast Pty Ltd	LC	Lohmann & Rauscher Pty Ltd
CU	Care Pharmaceuticals Pty Limited	LI	Luminarie Pty Ltd
DE	Stallergenes Australia Pty Ltd	LL	Astellas Pharma Australia Pty Ltd
DJ	De Fries Industries Pty Ltd	LM	Link Medical Products Pty Ltd
DO	Fair-Med Healthcare (Australia) Pty Ltd	LN	Aspen Pharmacare Australia Pty Limited
DQ	Church & Dwight (Australia) Pty Ltd	LO	Leo Pharma Pty Ltd
DV	Medical Developments International Limited	LQ	Astellas Pharma Australia Pty Ltd
DX	Ascensia Diabetes Care Australia Pty Ltd	LR	Cipla Australia Pty Ltd
DZ	Medsurge Healthcare Pty Ltd	LS	Astellas Pharma Australia Pty Ltd
EA	Amneal Pharmaceuticals Pty Ltd	LU	Lundbeck Australia Pty Ltd
ED	Amneal Pharmaceuticals Pty Ltd	LV	Luminarie Pty Ltd
EF	Amneal Pharmaceuticals Pty Ltd	LX	Lawley Pharmaceuticals Pty Ltd
EI	Eisai Australia Pty Ltd	LY	Eli Lilly Australia Pty Ltd
EL	Eli Lilly Australia Pty Ltd	MF	Mundipharma Pty Limited
EO	Ego Pharmaceuticals Proprietary Limited	MH	Molnlycke Health Care Pty Ltd
ER	Eris Pharmaceuticals (Australia) Pty Ltd	MK	Merck Sharp & Dohme (Australia) Pty Ltd
EU	Emerge Health Pty Ltd	MM	3M Pharmaceuticals Australia Pty Ltd
EV	Teva Pharma Australia Pty Limited	MT	Mentholatum Australasia Pty Ltd
EZ	Merz Australia Pty Ltd	MW	Biomed Aust Pty Limited
FB	Pierre Fabre Australia Pty Ltd	NE	Norgine Pty Limited
FF	Phebra Pty Ltd	NF	Novo Nordisk Pharmaceuticals Pty Limited
FG	Phebra Pty Ltd	NI	Novo Nordisk Pharmaceuticals Pty Limited
FI	Boehringer Ingelheim Pty Ltd	NM	Novartis Pharmaceuticals Australia Pty Limited
FK	A. Menarini Australia Pty Limited	NO	Novo Nordisk Pharmaceuticals Pty Limited
FM	Fawns and McAllan Proprietary Limited	NQ	Takeda Pharmaceuticals Australia Pty Ltd
FO	For Benefit Medicines Pty Ltd	NT	Nestle Australia Ltd
FP	Ferring Pharmaceuticals Pty Limited	NU	Nutricia Australia Pty Limited
FR	Merck Sharp & Dohme (Australia) Pty Ltd	NV	Novartis Pharmaceuticals Australia Pty Limited
FX	Gedeon Richter Australia Pty Ltd	OA	Orphan Australia Pty Ltd
FZ	Pfizer Australia Pty Ltd	OB	Oral B Laboratories Pty Ltd
GA	Galderma Australia Pty Ltd	OC	Accord Healthcare Pty Ltd
GC	GlaxoSmithKline Australia Pty Ltd	OD	Accord Healthcare Pty Ltd
GH	Amdipharm Mercury (Australia) Pty Limited	OE	Omegapharm Pty Ltd
GI	Gilead Sciences Pty Limited	OH	Orpharma Pty Ltd
GK	GlaxoSmithKline Australia Pty Ltd	OL	Owen Laboratories Division of Galderma Australia Pty Ltd
GN	Actavis Pty Ltd	OM	Colgate Oral Care
GO	Mylan Health Pty Ltd	ON	Orion Laboratories Pty Ltd
GQ	Generic Health Pty Ltd	OS	Otsuka Australia Pharmaceutical Pty Ltd
GT	Mylan Health Pty Ltd	OU	Oraderm Pharmaceuticals Pty Ltd

Code	Manufacturer
OW	Arrow Pharma Pty Ltd
PB	Pharmaco (Australia) Limited
PE	Allergan Australia Pty Limited
PF	Pfizer Australia Pty Ltd
PK	Fresenius Kabi Australia Pty Limited
PP	Petrus Pharmaceuticals Pty Ltd
PY	Procter & Gamble Pharmaceuticals Australia Pty Ltd
QA	Aspen Pharma Pty Ltd
QH	Cortex Health Pty Ltd
RA	Sun Pharma ANZ Pty Ltd
RB	Bio Revive Pty Ltd
RC	Reckitt Benckiser (Australia) Pty Limited
RF	Arrow Pharma Pty Ltd
RI	Dr Reddy's Laboratories (Australia) Pty Ltd
RJ	Recordati Rare Diseases Australia Pty. Ltd.
RN	Sun Pharma ANZ Pty Ltd
RO	Roche Products Pty Ltd
RW	Arrow Pharma Pty Ltd
RX	Servier Laboratories (Aust.) Pty Ltd
RZ	Dr Reddy's Laboratories (Australia) Pty Ltd
SA	SciGen (Australia) Pty Limited
SB	Nutricia Australia Pty Limited
SE	Servier Laboratories (Aust.) Pty Ltd
SG	Merck Serono Australia Pty Ltd
SI	Sigma Company Limited
SN	Smith & Nephew Pty Limited
SS	SSL Australia Pty Ltd
SW	sanofi-aventis Australia Pty Ltd
SY	Bayer Australia Ltd
SZ	Sandoz Pty Ltd
TB	Teva Pharma Australia Pty Limited
TD	STADA Pharmaceuticals Australia Pty Limited
TF	Te Arai BioFarma Limited
TK	Takeda Pharmaceuticals Australia Pty Ltd
TM	Technipro Marketing Pty Ltd
TS	Specialised Therapeutics Australia Pty Ltd
TT	Theramex Australia Pty Ltd
TW	Apotex Pty Ltd
TX	Apotex Pty Ltd
TY	Apotex Pty Ltd
UC	UCB Australia Proprietary Limited
UL	Bausch & Lomb (Australia) Pty Ltd
UM	Unomedical Pty Ltd
UN	Unilever Australia Limited
UO	Bausch & Lomb (Australia) Pty Ltd
UR	Camurus Pty Ltd
VE	AbbVie Pty Ltd
VF	VitaFlo Australia Pty Limited
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VL	Vifor Pharma Pty Limited
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APO-Indapamide SR(TX)	131	APO-Ramipril(TX)	142, 143
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<i>PROPRANOLOL</i>	135	<i>QUETIAPINE-AS XR(RW)</i>	756, 757
<i>PROPYLTHIOURACIL</i>	207	<i>Quetiapine-DRLA (RZ)</i>	756
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