



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 May 2019



Fees, Patient Contributions and Safety Net Thresholds

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

Dispensing Fees:	Ready-prepared	\$7.29
	Dangerous drug fee	\$3.07
	Extemporaneously-prepared	\$9.33
	Allowable additional patient charge*	\$4.53
Additional Fees (for safety net prices):	Ready-prepared	\$1.23
	Extemporaneously-prepared	\$1.59
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 May 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

Alterations

Alteration – Item Description

From 3453R	ATROPINE SULFATE MONOHYDRATE , atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules (<i>Pfizer Australia Pty Ltd</i>)
To 3453R	ATROPINE SULFATE , atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules (<i>Pfizer Australia Pty Ltd</i>)
From 3463G	DIPHTHERIA TOXOID + TETANUS TOXOID , diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes (<i>ADT Booster</i>)
To 3463G	DIPHTHERIA + TETANUS VACCINE , diphtheria 2 units + tetanus 20 units vaccine injection, 5 x 0.5 mL syringes (<i>ADT Booster</i>)

General Pharmaceutical Benefits

Additions

Addition – Item

11684Y	ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL pen devices (<i>Orencia ClickJect</i>)
11693K	ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL pen devices (<i>Orencia ClickJect</i>)
11687D	ESOMEPRAZOLE , esomeprazole 20 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
11692J	ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30 (<i>Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Nexazole, Nexium, Nexole, Pharmacor Esomeprazole</i>)
11694L	LACOSAMIDE , lacosamide 10 mg/mL oral liquid, 200 mL (<i>Vimpat</i>)
11669E	LANSOPRAZOLE , lansoprazole 30 mg enteric capsule, 28 (<i>APO-Lansoprazole, Lanzopran, Zopral</i>)
11697P	LANSOPRAZOLE , lansoprazole 30 mg orally disintegrating tablet, 28 (<i>APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs</i>)
11682W	OMEPRAZOLE , omeprazole 20 mg enteric capsule, 30 (<i>APO-Omeprazole, Maxor, Omeprazole Sandoz, Pemzo, Pharmacor Omeprazole 20, Probitor</i>)
11677N	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>Acimax Tablets, Losec Tablets, Omepral, Omeprazole Sandoz</i>)
11683X	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>APO-Omeprazole, Chem mart Omeprazole, Meprazol, Omeprazole AN, Omeprazole generichealth, Ozmepr, Pharmacor Omeprazole, Terry White Chemists Omeprazole</i>)
11699R	PALBOCICLIB , palbociclib 75 mg capsule, 21 (<i>Ibrance</i>)
11700T	PALBOCICLIB , palbociclib 100 mg capsule, 21 (<i>Ibrance</i>)
11698Q	PALBOCICLIB , palbociclib 125 mg capsule, 21 (<i>Ibrance</i>)
11678P	PANTOPRAZOLE , pantoprazole 40 mg enteric coated granules, 30 sachets (<i>Somac</i>)

11681T	PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30 (<i>APO-Pantoprazole, APOTEX-Pantoprazole, I-Pantoprazole, Ozpan, Panthron, Panto, Pantoprazole AN, Pantoprazole Actavis, Pantoprazole GH, Pantoprazole Sandoz, Pantoprazole generichealth, Salpraz, Somac, Sozol</i>)
11670F	RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30 (<i>APO-Rabeprazole, Chem mart Rabeprazole, Parbezol, Pariet, Parzol 20, Rabeprazole AN, Rabeprazole SUN, Rabeprazole Sandoz, Rabeprazole-DRLA, Terry White Chemists Rabeprazole, Zabep</i>)
11676M	SAPROPTERIN , sapropterin dihydrochloride 100 mg soluble tablet, 30 (<i>Kuvan</i>)
11686C	SAPROPTERIN , sapropterin dihydrochloride 100 mg soluble tablet, 30 (<i>Kuvan</i>)
11691H	SAPROPTERIN , sapropterin dihydrochloride 100 mg soluble tablet, 30 (<i>Kuvan</i>)
11675L	TOFACITINIB , tofacitinib 5 mg tablet, 56 (<i>Xeljanz</i>)
11690G	TOFACITINIB , tofacitinib 5 mg tablet, 56 (<i>Xeljanz</i>)

Addition – Brand

2751T	<i>Amlodipine APOTEX, GX</i> – AMLODIPINE , amlodipine 5 mg tablet, 30
2751T	<i>BTC Amlodipine, JB</i> – AMLODIPINE , amlodipine 5 mg tablet, 30
2752W	<i>Amlodipine APOTEX, GX</i> – AMLODIPINE , amlodipine 10 mg tablet, 30
2752W	<i>BTC Amlodipine, JB</i> – AMLODIPINE , amlodipine 10 mg tablet, 30
9155W	<i>Duloxecor, CR</i> – DULOXETINE , duloxetine 30 mg enteric capsule, 28
9156X	<i>Duloxecor, CR</i> – DULOXETINE , duloxetine 60 mg enteric capsule, 28
9483D	<i>Pharmacor Ezetimibe Simvastatin 10/10, CR</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 10 mg tablet, 30
9484E	<i>Pharmacor Ezetimibe Simvastatin 10/20, CR</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 20 mg tablet, 30
8881K	<i>Pharmacor Ezetimibe Simvastatin 10/40, CR</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 40 mg tablet, 30
8882L	<i>Pharmacor Ezetimibe Simvastatin 10/80, CR</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 80 mg tablet, 30
1558B	<i>ISOBIDE MR, RF</i> – ISOSORBIDE MONONITRATE , isosorbide mononitrate 60 mg modified release tablet, 30
8534E	<i>BTC Lercanidipine, JB</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
8534E	<i>Lercanidipine APOTEX, GX</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
8679T	<i>BTC Lercanidipine, JB</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
8679T	<i>Lercanidipine APOTEX, GX</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
1594X	<i>Ondansetron APOTEX, GX</i> – ONDANSETRON , ondansetron 4 mg tablet, 10
8224W	<i>Ondansetron APOTEX, GX</i> – ONDANSETRON , ondansetron 4 mg tablet, 4
1595Y	<i>Ondansetron APOTEX, GX</i> – ONDANSETRON , ondansetron 8 mg tablet, 10
8225X	<i>Ondansetron APOTEX, GX</i> – ONDANSETRON , ondansetron 8 mg tablet, 4
1952R	<i>Rasagiline-Teva, EV</i> – RASAGILINE , rasagiline 1 mg tablet, 30

Addition – Note

10343J	ESOMEPRAZOLE , esomeprazole 20 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
10330Q	ESOMEPRAZOLE , esomeprazole 40 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
10331R	ESOMEPRAZOLE , esomeprazole 40 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
8600P	ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30 (<i>Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Nexazole, Nexium, Nexole, Pharmacor Esomeprazole</i>)
3401B	ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30 (<i>Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Nexazole, Nexium, Nexole, Pharmacor Esomeprazole</i>)

8601Q	ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30 (<i>Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Nexazole, Nexium, Nexole, Pharmacor Esomeprazole</i>)
8198L	LANSOPRAZOLE , lansoprazole 15 mg enteric capsule, 30 (<i>Zopral</i>)
2241Y	LANSOPRAZOLE , lansoprazole 30 mg enteric capsule, 28 (<i>APO-Lansoprazole, Lanzopran, Zopral</i>)
9331D	LANSOPRAZOLE , lansoprazole 15 mg orally disintegrating tablet, 28 (<i>APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs</i>)
9478W	LANSOPRAZOLE , lansoprazole 30 mg orally disintegrating tablet, 28 (<i>APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs</i>)
1327W	OMEPRAZOLE , omeprazole 20 mg enteric capsule, 30 (<i>APO-Omeprazole, Maxor, Omeprazole Sandoz, Pemzo, Pharmacor Omeprazole 20, Probitor</i>)
8332M	OMEPRAZOLE , omeprazole 10 mg enteric tablet, 30 (<i>Losec Tablets</i>)
8333N	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>APO-Omeprazole, Chem mart Omeprazole, Meprazol, Omeprazole AN, Omeprazole generichealth, Ozmepr, Pharmacor Omeprazole, Terry White Chemists Omeprazole</i>)
9110L	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>Acimax Tablets, Losec Tablets, Omepral, Omeprazole Sandoz</i>)
9424B	PANTOPRAZOLE , pantoprazole 40 mg enteric coated granules, 30 sachets (<i>Somac</i>)
8399C	PANTOPRAZOLE , pantoprazole 20 mg enteric tablet, 30 (<i>APO-Pantoprazole, APOTEX-Pantoprazole, Ozpan, Panthron, Panto, Pantofast 20, Pantoprazole AN, Pantoprazole APOTEX, , Pantoprazole Sandoz, Pantoprazole generichealth, Salpraz, Somac, Sozol</i>)
8008L	PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30 (<i>APO-Pantoprazole, APOTEX-Pantoprazole, I-Pantoprazole, Ozpan, Panthron, Panto, Pantoprazole AN, Pantoprazole APOTEX, Pantoprazole Actavis, Pantoprazole GH, Pantoprazole Sandoz, Pantoprazole generichealth, Salpraz, Somac, Sozol</i>)
8507R	RABEPRAZOLE , rabeprazole sodium 10 mg enteric tablet, 28 (<i>APO-Rabeprazole, Parbezol, Pariet, Parzol 10, Rabeprazole AN, Rabeprazole Sandoz, Rabeprazole-DRLA</i>)
8508T	RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30 (<i>APO-Rabeprazole, Chem mart Rabeprazole, Parbezol, Pariet, Parzol 20, Rabeprazole AN, Rabeprazole SUN, Rabeprazole Sandoz, Rabeprazole-DRLA, Terry White Chemists Rabeprazole, Zabep</i>)

Deletions

Deletion – Item

11068M	ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL syringes (<i>Orencia ClickJect</i>)
11092T	ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL syringes (<i>Orencia ClickJect</i>)
8727H	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE , amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 50 g sachets (<i>XP Maxamum</i>)
8554F	AMINO ACID FORMULA WITHOUT PHENYLALANINE , amino acid formula without phenylalanine 500 mg capsule, 200 (<i>Phlexy-10</i>)
2347M	AMINO ACID FORMULA WITHOUT PHENYLALANINE , amino acid formula without phenylalanine powder for oral liquid, 30 x 20 g sachets (<i>Phlexy-10 Drink Mix</i>)
8132B	CLODRONATE , clodronate sodium 400 mg capsule, 100 (<i>Bonefos</i>)
8265B	CLODRONATE , clodronate sodium 800 mg tablet, 60 (<i>Bonefos 800 mg</i>)
1037N	OLANZAPINE , olanzapine 5 mg tablet, 28 (<i>Olanzapine generichealth 5</i>)
1042W	OLANZAPINE , olanzapine 10 mg tablet, 28 (<i>Olanzapine generichealth 10</i>)
11034R	OLAPARIB , olaparib 50 mg capsule, 4 x 112 (<i>Lynparza</i>)
5527X	POLYVINYL ALCOHOL , polyvinyl alcohol 1.4% eye drops, 15 mL (<i>Vistil</i>)
8831T	POLYVINYL ALCOHOL , polyvinyl alcohol 1.4% eye drops, 15 mL (<i>Vistil</i>)
9221H	POLYVINYL ALCOHOL , polyvinyl alcohol 1.4% eye drops, 15 mL (<i>Vistil</i>)
5528Y	POLYVINYL ALCOHOL , polyvinyl alcohol 3% eye drops, 15 mL (<i>Vistil Forte</i>)
8832W	POLYVINYL ALCOHOL , polyvinyl alcohol 3% eye drops, 15 mL (<i>Vistil Forte</i>)
9223K	POLYVINYL ALCOHOL , polyvinyl alcohol 3% eye drops, 15 mL (<i>Vistil Forte</i>)

Deletion – Brand

1210Q	<i>Cifran, RA</i> – CIPROFLOXACIN , ciprofloxacin 750 mg tablet, 14
2850B	<i>Lamotrigine generichealth, HQ</i> – LAMOTRIGINE , lamotrigine 100 mg tablet, 56
2851C	<i>Lamotrigine generichealth, HQ</i> – LAMOTRIGINE , lamotrigine 200 mg tablet, 56
8679T	<i>Lercanidipine GH, GQ</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
8399C	<i>Pantoprazole GH, GQ</i> – PANTOPRAZOLE , pantoprazole 20 mg enteric tablet, 30
5261X	<i>Roxithromycin GH, GQ</i> – ROXITHROMYCIN , roxithromycin 300 mg tablet, 5
8016X	<i>Roxithromycin GH, GQ</i> – ROXITHROMYCIN , roxithromycin 300 mg tablet, 5

Deletion – Note

10238W	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (<i>Cimzia</i>)
10896L	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (<i>Cimzia</i>)
10909E	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (<i>Cimzia</i>)
11323Y	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (<i>Cimzia</i>)
11324B	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (<i>Cimzia</i>)
11326D	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (<i>Cimzia</i>)
8185T	OLANZAPINE , olanzapine 5 mg tablet, 28 (<i>APO-Olanzapine, Chem mart Olanzapine, Olanzapine AN, Olanzapine APOTEX, Olanzapine RBX, Olanzapine Sandoz, Olanzapine-DRLA, Ozin 5, PRYZEX, Terry White Chemists Olanzapine, Zypine, Zyprexa</i>)
8187X	OLANZAPINE , olanzapine 10 mg tablet, 28 (<i>APO-Olanzapine, Chem mart Olanzapine, Olanzapine AN, Olanzapine APOTEX, Olanzapine RBX, Olanzapine Sandoz, Olanzapine-DRLA, Ozin 10, PRYZEX, Terry White Chemists Olanzapine, Zypine, Zyprexa</i>)

Alterations

Alteration – Item Description

From	
10397F	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges (<i>Humira</i>)
To	
10397F	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices (<i>Humira</i>)
From	
10400J	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To	
10400J	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From	
10413C	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To	
10413C	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From	
10420K	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To	
10420K	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From	
10945C	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges (<i>Humira</i>)
To	
10945C	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices (<i>Humira</i>)
From	
10955N	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To	
10955N	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From	
10961X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To	
10961X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)

From 11132X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges (<i>Humira</i>)
To 11132X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices (<i>Humira</i>)
From 11133Y	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL cartridges (<i>Humira</i>)
To 11133Y	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL pen devices (<i>Humira</i>)
From 11137E	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL cartridges (<i>Humira</i>)
To 11137E	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL pen devices (<i>Humira</i>)
From 5282B	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 5282B	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 5284D	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 5284D	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 8962Q	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges (<i>Humira</i>)
To 8962Q	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices (<i>Humira</i>)
From 8965W	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 8965W	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 8966X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 8966X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 9099X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 9099X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 9100Y	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 9100Y	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 9101B	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 9101B	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 9102C	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 9102C	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 9103D	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 9103D	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 9104E	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 9104E	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 9187M	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges (<i>Humira</i>)
To 9187M	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices (<i>Humira</i>)

From 9190Q	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 9190Q	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 9191R	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 9191R	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 9426D	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 9426D	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 9428F	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
To 9428F	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
From 1093M	ATROPINE SULFATE MONOHYDRATE , atropine sulfate monohydrate 1% eye drops, 15 mL (<i>Atropt</i>)
To 1093M	ATROPINE SULFATE , atropine sulfate monohydrate 1% eye drops, 15 mL (<i>Atropt</i>)
From 1089H	ATROPINE SULFATE MONOHYDRATE , atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules (<i>Pfizer Australia Pty Ltd</i>)
To 1089H	ATROPINE SULFATE , atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules (<i>Pfizer Australia Pty Ltd</i>)
From 5022H	ATROPINE SULFATE MONOHYDRATE , atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules (<i>Pfizer Australia Pty Ltd</i>)
To 5022H	ATROPINE SULFATE , atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules (<i>Pfizer Australia Pty Ltd</i>)
From 2694T	BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE , betamethasone (as sodium phosphate) 2.96 mg/mL + betamethasone (as acetate) 2.71 mg/mL injection, 5 x 1 mL ampoules (<i>Celestone Chronodose</i>)
To 2694T	BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE , betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules (<i>Celestone Chronodose</i>)
From 5034Y	BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE , betamethasone (as sodium phosphate) 2.96 mg/mL + betamethasone (as acetate) 2.71 mg/mL injection, 5 x 1 mL ampoules (<i>Celestone Chronodose</i>)
To 5034Y	BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE , betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules (<i>Celestone Chronodose</i>)
From 8315P	CEFEPIME , CEFEPIME Powder for injection 1 g (as hydrochloride), 1 (<i>Cefepime Kabi, Cefepime-AFT, Cefepime Alphapharm, DBL Cefepime, Omegapharm Pty Ltd</i>)
To 8315P	CEFEPIME , cefepime 1 g injection, 1 vial (<i>Cefepime Kabi, Cefepime-AFT, Cefepime Alphapharm, DBL Cefepime, Omegapharm Pty Ltd</i>)
From 8316Q	CEFEPIME , CEFEPIME Powder for injection 2 g (as hydrochloride), 1 (<i>Cefepime Kabi, Cefepime-AFT, Cefepime Alphapharm, DBL Cefepime, Omegapharm Pty Ltd</i>)
To 8316Q	CEFEPIME , cefepime 2 g injection, 1 vial (<i>Cefepime Kabi, Cefepime-AFT, Cefepime Alphapharm, DBL Cefepime, Omegapharm Pty Ltd</i>)

From 5481L	CITRULLINE WITH CARBOHYDRATE , citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets (<i>Citrulline 1000</i>)
To 5481L	CITRULLINE WITH CARBOHYDRATE , citrulline with carbohydrate containing 1 g citrulline powder for oral liquid, 30 x 4 g sachets (<i>Citrulline 1000</i>)
From 2501P	DIPHENOXYLATE + ATROPINE SULFATE MONOHYDRATE , diphenoxylate hydrochloride 2.5 mg + atropine sulfate monohydrate 25 microgram tablet, 20 (<i>Lofenoxal, Lomotil</i>)
To 2501P	DIPHENOXYLATE + ATROPINE SULFATE , diphenoxylate hydrochloride 2.5 mg + atropine sulfate monohydrate 25 microgram tablet, 20 (<i>Lofenoxal, Lomotil</i>)
From 8783G	DIPHTHERIA TOXOID + TETANUS TOXOID , diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes (<i>ADT Booster</i>)
To 8783G	DIPHTHERIA + TETANUS VACCINE , diphtheria 2 units + tetanus 20 units vaccine injection, 5 x 0.5 mL syringes (<i>ADT Booster</i>)
From 10195N	GLYCINE WITH CARBOHYDRATE , glycine with carbohydrate containing 500 mg of glycine oral liquid: powder for, 30 x 4 g sachets (<i>Glycine500</i>)
To 10195N	GLYCINE WITH CARBOHYDRATE , glycine with carbohydrate containing 500 mg glycine powder for oral liquid, 30 x 4 g sachets (<i>Glycine500</i>)
From 10126Y	MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE , macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL (<i>Movicol Liquid</i>)
To 10126Y	MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE , 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 (<i>Movicol Liquid</i>)
From 8612G	MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets (<i>APO-MACROGOL plus ELECTROLYTES, Chemists' Own Macrogol with Electrolytes, LaxaCon, Macrovic, Molaxole, Movicol, lax-sachets</i>)
To 8612G	MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE , 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 (<i>APO-MACROGOL plus ELECTROLYTES, Chemists' Own Macrogol with Electrolytes, LaxaCon, Macrovic, Molaxole, Movicol, lax-sachets</i>)
From 10687L	NADROPARIN , nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes (<i>Fraxiparine</i>)
To 10687L	NADROPARIN , nadroparin calcium 1900 anti-Xa units/0.2 mL injection, 2 x 0.2 mL syringes (<i>Fraxiparine</i>)
From 10735B	NADROPARIN , nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes (<i>Fraxiparine</i>)
To 10735B	NADROPARIN , nadroparin calcium 1900 anti-Xa units/0.2 mL injection, 2 x 0.2 mL syringes (<i>Fraxiparine</i>)
From 10686K	NADROPARIN , nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes (<i>Fraxiparine</i>)
To 10686K	NADROPARIN , nadroparin calcium 2850 anti-Xa units/0.3 mL injection, 2 x 0.3 mL syringes (<i>Fraxiparine</i>)
From 10701F	NADROPARIN , nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes (<i>Fraxiparine</i>)
To 10701F	NADROPARIN , nadroparin calcium 2850 anti-Xa units/0.3 mL injection, 2 x 0.3 mL syringes (<i>Fraxiparine</i>)

From 10685J	NADROPARIN , nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes (<i>Fraxiparine</i>)
To 10685J	NADROPARIN , nadroparin calcium 3800 anti-Xa units/0.4 mL injection, 2 x 0.4 mL syringes (<i>Fraxiparine</i>)
From 10717C	NADROPARIN , nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes (<i>Fraxiparine</i>)
To 10717C	NADROPARIN , nadroparin calcium 3800 anti-Xa units/0.4 mL injection, 2 x 0.4 mL syringes (<i>Fraxiparine</i>)
From 10716B	NADROPARIN , nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes (<i>Fraxiparine</i>)
To 10716B	NADROPARIN , nadroparin calcium 5700 anti-Xa units/0.6 mL injection, 2 x 0.6 mL syringes (<i>Fraxiparine</i>)
From 10718D	NADROPARIN , nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes (<i>Fraxiparine</i>)
To 10718D	NADROPARIN , nadroparin calcium 5700 anti-Xa units/0.6 mL injection, 2 x 0.6 mL syringes (<i>Fraxiparine</i>)
From 10734Y	NADROPARIN , nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes (<i>Fraxiparine</i>)
To 10734Y	NADROPARIN , nadroparin calcium 7600 anti-Xa units/0.8 mL injection, 2 x 0.8 mL syringes (<i>Fraxiparine</i>)
From 10740G	NADROPARIN , nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes (<i>Fraxiparine</i>)
To 10740G	NADROPARIN , nadroparin calcium 7600 anti-Xa units/0.8 mL injection, 2 x 0.8 mL syringes (<i>Fraxiparine</i>)
From 10702G	NADROPARIN , nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes (<i>Fraxiparine</i>)
To 10702G	NADROPARIN , nadroparin calcium 9500 anti-Xa units/mL injection, 2 x 1 mL syringes (<i>Fraxiparine</i>)
From 10733X	NADROPARIN , nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes (<i>Fraxiparine</i>)
To 10733X	NADROPARIN , nadroparin calcium 9500 anti-Xa units/mL injection, 2 x 1 mL syringes (<i>Fraxiparine</i>)
From 10706L	NADROPARIN , nadroparin calcium 11 400 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes (<i>Fraxiparine Forte</i>)
To 10706L	NADROPARIN , nadroparin calcium 11 400 anti-Xa units/0.6 mL injection, 2 x 0.6 mL syringes (<i>Fraxiparine Forte</i>)
From 10725L	NADROPARIN , nadroparin calcium 15 200 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes (<i>Fraxiparine Forte</i>)
To 10725L	NADROPARIN , nadroparin calcium 15 200 anti-Xa units/0.8 mL injection, 2 x 0.8 mL syringes (<i>Fraxiparine Forte</i>)
From 10707M	NADROPARIN , nadroparin calcium 19 000 anti-Xa international units/mL injection, 2 x 1 mL syringes (<i>Fraxiparine Forte</i>)
To 10707M	NADROPARIN , nadroparin calcium 19 000 anti-Xa units/mL injection, 2 x 1 mL syringes (<i>Fraxiparine Forte</i>)
From 10205D	TESTOSTERONE UNDECANOATE , testosterone undecanoate 1 g/4 mL injection, 4 mL vial (<i>Reandron 1000</i>)
To 10205D	TESTOSTERONE UNDECANOATE , testosterone undecanoate 1 g/4 mL modified release injection, 4 mL vial (<i>Reandron 1000</i>)

From 2971J	TRIAMCINOLONE + NEOMYCIN SULFATE + GRAMICIDIN + NYSTATIN , triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/mL ear drops, 7.5 mL (<i>Kenacomb Otic, Otocomb Otic</i>)
To 2971J	TRIAMCINOLONE + NEOMYCIN + GRAMICIDIN + NYSTATIN , triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/mL ear drops, 7.5 mL (<i>Kenacomb Otic, Otocomb Otic</i>)
From 2974M	TRIAMCINOLONE + NEOMYCIN SULFATE + GRAMICIDIN + NYSTATIN , triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 5 g (<i>Kenacomb Otic, Otocomb Otic</i>)
To 2974M	TRIAMCINOLONE + NEOMYCIN + GRAMICIDIN + NYSTATIN , triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 5 g (<i>Kenacomb Otic, Otocomb Otic</i>)
From 9308X	TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER , triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cans (<i>ProZero</i>)
To 9308X	TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER , triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cartons (<i>ProZero</i>)
From 9309Y	TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER , triglycerides long chain with glucose polymer oral liquid, 6 x 1 L bottles (<i>ProZero</i>)
To 9309Y	TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER , triglycerides long chain with glucose polymer oral liquid, 6 x 1 L cartons (<i>ProZero</i>)

Alteration – Note

9425C	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Humira</i>)
9426D	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
9427E	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Humira</i>)
9428F	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Humira</i>)
8750M	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations (<i>Symbicort Turbuhaler 400/12</i>)
10295W	ESOMEPRAZOLE , esomeprazole 20 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
8886Q	ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30 (<i>Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Nexazole, Nexium, Nexole, Pharmacor Esomeprazole</i>)
11223Q	ETANERCEPT , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
9037P	ETANERCEPT , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
9429G	ETANERCEPT , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
11221N	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys</i>)
11222P	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
9461Y	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
9462B	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
11224R	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
11225T	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i>)
9091L	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
9431J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
11614G	GUSELKUMAB , guselkumab 100 mg/mL injection, 1 mL syringe (<i>Tremfya</i>)
11032P	IXEKIZUMAB , ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices (<i>Taltz</i>)
11033Q	IXEKIZUMAB , ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices (<i>Taltz</i>)
9337K	LACOSAMIDE , lacosamide 150 mg tablet, 56 (<i>Vimpat</i>)

9338L	LACOSAMIDE , lacosamide 200 mg tablet, 56 (<i>Vimpat</i>)
2240X	LANSOPRAZOLE , lansoprazole 30 mg enteric capsule, 28 (<i>APO-Lansoprazole, Lanzopran, Zopral</i>)
9477T	LANSOPRAZOLE , lansoprazole 30 mg orally disintegrating tablet, 28 (<i>APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs</i>)
1326T	OMEPRAZOLE , omeprazole 20 mg enteric capsule, 30 (<i>APO-Omeprazole, Maxor, Omeprazole Sandoz, Pemzo, Pharmacor Omeprazole 20, Probitor</i>)
8331L	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>APO-Omeprazole, Chem mart Omeprazole, Meprazol, Omeprazole AN, Omeprazole generichealth, Ozmepr, Pharmacor Omeprazole, Terry White Chemists Omeprazole</i>)
9109K	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>Acimax Tablets, Losec Tablets, Omepral, Omeprazole Sandoz</i>)
9423Y	PANTOPRAZOLE , pantoprazole 40 mg enteric coated granules, 30 sachets (<i>Somac</i>)
8007K	PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30 (<i>APO-Pantoprazole, APOTEX-Pantoprazole, I-Pantoprazole, Ozpan, Panthron, Panto, Pantoprazole AN, Pantoprazole APOTEX, Pantoprazole Actavis, Pantoprazole GH, Pantoprazole Sandoz, Pantoprazole generichealth, Salpraz, Somac, Sozol</i>)
10520Q	PONATINIB , ponatinib 15 mg tablet, 60 (<i>Iclusig</i>)
10530F	PONATINIB , ponatinib 45 mg tablet, 30 (<i>Iclusig</i>)
8509W	RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30 (<i>APO-Rabeprazole, Chem mart Rabeprazole, Parbezol, Pariet, Parzol 20, Rabeprazole AN, Rabeprazole SUN, Rabeprazole Sandoz, Rabeprazole-DRLA, Terry White Chemists Rabeprazole, Zabep</i>)
10425Q	SECUKINUMAB , secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (<i>Cosentyx</i>)
10494H	SECUKINUMAB , secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (<i>Cosentyx</i>)
10910F	SECUKINUMAB , secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (<i>Cosentyx</i>)
11613F	TILDRAKIZUMAB , tildrakizumab 100 mg/mL injection, 1 mL syringe (<i>Ilumya</i>)
11616J	TILDRAKIZUMAB , tildrakizumab 100 mg/mL injection, 1 mL syringe (<i>Ilumya</i>)
9304Q	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Stelara</i>)
9305R	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Stelara</i>)

Alteration – Restriction

9425C	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Humira</i>)
9426D	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devicescartridges (<i>Humira</i>)
9427E	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Humira</i>)
9428F	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devicescartridges (<i>Humira</i>)
10295W	ESOMEPRAZOLE , esomeprazole 20 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
10343J	ESOMEPRAZOLE , esomeprazole 20 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
10330Q	ESOMEPRAZOLE , esomeprazole 40 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
10331R	ESOMEPRAZOLE , esomeprazole 40 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
8600P	ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30 (<i>Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Nexazole, Nexium, Nexole, Pharmacor Esomeprazole</i>)
8886Q	ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30 (<i>Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Nexazole, Nexium, Nexole, Pharmacor Esomeprazole</i>)
3401B	ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30 (<i>Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Nexazole, Nexium, Nexole, Pharmacor Esomeprazole</i>)
8601Q	ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30 (<i>Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Nexazole, Nexium, Nexole, Pharmacor Esomeprazole</i>)
11223Q	ETANERCEPT , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
9037P	ETANERCEPT , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)

9429G	ETANERCEPT , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
11221N	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys</i>)
11222P	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
9461Y	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys</i> , <i>Enbrel</i>)
9462B	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys</i> , <i>Enbrel</i>)
11224R	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
11225T	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i>)
9091L	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i> , <i>Enbrel</i>)
9431J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i> , <i>Enbrel</i>)
10445R	FEBUXOSTAT , febuxostat 80 mg tablet, 28 (<i>Adenuric</i>)
11614G	GUSELKUMAB , guselkumab 100 mg/mL injection, 1 mL syringe (<i>Tremfya</i>)
11032P	IXEKIZUMAB , ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices (<i>Taltz</i>)
11033Q	IXEKIZUMAB , ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices (<i>Taltz</i>)
10293R	LACOSAMIDE , lacosamide 50 mg tablet, 14 (<i>Vimpat</i>)
9333F	LACOSAMIDE , lacosamide 50 mg tablet, 14 (<i>Vimpat</i>)
9334G	LACOSAMIDE , lacosamide 100 mg tablet, 14 (<i>Vimpat</i>)
9335H	LACOSAMIDE , lacosamide 100 mg tablet, 56 (<i>Vimpat</i>)
9336J	LACOSAMIDE , lacosamide 150 mg tablet, 14 (<i>Vimpat</i>)
9337K	LACOSAMIDE , lacosamide 150 mg tablet, 56 (<i>Vimpat</i>)
9338L	LACOSAMIDE , lacosamide 200 mg tablet, 56 (<i>Vimpat</i>)
2240X	LANSOPRAZOLE , lansoprazole 30 mg enteric capsule, 28 (<i>APO-Lansoprazole</i> , <i>Lanzopran</i> , <i>Zopral</i>)
2241Y	LANSOPRAZOLE , lansoprazole 30 mg enteric capsule, 28 (<i>APO-Lansoprazole</i> , <i>Lanzopran</i> , <i>Zopral</i>)
9477T	LANSOPRAZOLE , lansoprazole 30 mg orally disintegrating tablet, 28 (<i>APO-Lansoprazole ODT</i> , <i>Lansoprazole ODT GH</i> , <i>Zopral ODT</i> , <i>Zoton FasTabs</i>)
9478W	LANSOPRAZOLE , lansoprazole 30 mg orally disintegrating tablet, 28 (<i>APO-Lansoprazole ODT</i> , <i>Lansoprazole ODT GH</i> , <i>Zopral ODT</i> , <i>Zoton FasTabs</i>)
1326T	OMEPRAZOLE , omeprazole 20 mg enteric capsule, 30 (<i>APO-Omeprazole</i> , <i>Maxor</i> , <i>Omeprazole Sandoz</i> , <i>Pemzo</i> , <i>Pharmacor Omeprazole 20</i> , <i>Probitor</i>)
1327W	OMEPRAZOLE , omeprazole 20 mg enteric capsule, 30 (<i>APO-Omeprazole</i> , <i>Maxor</i> , <i>Omeprazole Sandoz</i> , <i>Pemzo</i> , <i>Pharmacor Omeprazole 20</i> , <i>Probitor</i>)
8331L	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>APO-Omeprazole</i> , <i>Chem mart Omeprazole</i> , <i>Meprazol</i> , <i>Omeprazole AN</i> , <i>Omeprazole generichealth</i> , <i>Ozmep</i> , <i>Pharmacor Omeprazole</i> , <i>Terry White Chemists Omeprazole</i>)
8333N	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>APO-Omeprazole</i> , <i>Chem mart Omeprazole</i> , <i>Meprazol</i> , <i>Omeprazole AN</i> , <i>Omeprazole generichealth</i> , <i>Ozmep</i> , <i>Pharmacor Omeprazole</i> , <i>Terry White Chemists Omeprazole</i>)
9109K	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>Acimax Tablets</i> , <i>Losec Tablets</i> , <i>Omepral</i> , <i>Omeprazole Sandoz</i>)
9110L	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>Acimax Tablets</i> , <i>Losec Tablets</i> , <i>Omepral</i> , <i>Omeprazole Sandoz</i>)
9423Y	PANTOPRAZOLE , pantoprazole 40 mg enteric coated granules, 30 sachets (<i>Somac</i>)
9424B	PANTOPRAZOLE , pantoprazole 40 mg enteric coated granules, 30 sachets (<i>Somac</i>)
8007K	PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30 (<i>APO-Pantoprazole</i> , <i>APOTEX-Pantoprazole</i> , <i>I-Pantoprazole</i> , <i>Ozpan</i> , <i>Panthron</i> , <i>Panto</i> , <i>Pantoprazole AN</i> , <i>Pantoprazole APOTEX</i> , <i>Pantoprazole Actavis</i> , <i>Pantoprazole GH</i> , <i>Pantoprazole Sandoz</i> , <i>Pantoprazole generichealth</i> , <i>Salpraz</i> , <i>Somac</i> , <i>Sozol</i>)
8008L	PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30 (<i>APO-Pantoprazole</i> , <i>APOTEX-Pantoprazole</i> , <i>I-Pantoprazole</i> , <i>Ozpan</i> , <i>Panthron</i> , <i>Panto</i> , <i>Pantoprazole AN</i> , <i>Pantoprazole APOTEX</i> , <i>Pantoprazole Actavis</i> , <i>Pantoprazole GH</i> , <i>Pantoprazole Sandoz</i> , <i>Pantoprazole generichealth</i> , <i>Salpraz</i> , <i>Somac</i> , <i>Sozol</i>)
10520Q	PONATINIB , ponatinib 15 mg tablet, 60 (<i>Iclusig</i>)
10530F	PONATINIB , ponatinib 45 mg tablet, 30 (<i>Iclusig</i>)

8508T	RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30 (<i>APO-Rabeprazole, Chem mart Rabeprazole, Parbezol, Pariet, Parzol 20, Rabeprazole AN, Rabeprazole SUN, Rabeprazole Sandoz, Rabeprazole-DRLA, Terry White Chemists Rabeprazole, Zabep</i>)
8509W	RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30 (<i>APO-Rabeprazole, Chem mart Rabeprazole, Parbezol, Pariet, Parzol 20, Rabeprazole AN, Rabeprazole SUN, Rabeprazole Sandoz, Rabeprazole-DRLA, Terry White Chemists Rabeprazole, Zabep</i>)
11385F	RIBOCICLIB , ribociclib 200 mg tablet, 21 (<i>Kisqali</i>)
11386G	RIBOCICLIB , ribociclib 200 mg tablet, 63 (<i>Kisqali</i>)
11397W	RIBOCICLIB , ribociclib 200 mg tablet, 42 (<i>Kisqali</i>)
10425Q	SECUKINUMAB , secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (<i>Cosentyx</i>)
10494H	SECUKINUMAB , secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (<i>Cosentyx</i>)
10910F	SECUKINUMAB , secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (<i>Cosentyx</i>)
11613F	TILDRAKIZUMAB , tildrakizumab 100 mg/mL injection, 1 mL syringe (<i>Ilumya</i>)
11616J	TILDRAKIZUMAB , tildrakizumab 100 mg/mL injection, 1 mL syringe (<i>Ilumya</i>)
9304Q	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Stelara</i>)
9305R	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Stelara</i>)

Alteration – Restriction Level

		<i>From</i>	<i>To</i>
10295W	ESOMEPRAZOLE , esomeprazole 20 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)	restricted	streamlined
10343J	ESOMEPRAZOLE , esomeprazole 20 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)	restricted	streamlined
10330Q	ESOMEPRAZOLE , esomeprazole 40 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)	restricted	authority-required
8600P	ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30 (<i>Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Nexazole, Nexium, Nexole, Pharmacor Esomeprazole</i>)	restricted	streamlined
8886Q	ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30 (<i>Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Nexazole, Nexium, Nexole, Pharmacor Esomeprazole</i>)	restricted	streamlined
8601Q	ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30 (<i>Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Nexazole, Nexium, Nexole, Pharmacor Esomeprazole</i>)	restricted	authority-required
10445R	FEBUXOSTAT , febuxostat 80 mg tablet, 28 (<i>Adenuric</i>)	authority-required	streamlined
2240X	LANSOPRAZOLE , lansoprazole 30 mg enteric capsule, 28 (<i>APO-Lansoprazole, Lanzopran, Zopral</i>)	restricted	streamlined
2241Y	LANSOPRAZOLE , lansoprazole 30 mg enteric capsule, 28 (<i>APO-Lansoprazole, Lanzopran, Zopral</i>)	restricted	streamlined
9477T	LANSOPRAZOLE , lansoprazole 30 mg orally disintegrating tablet, 28 (<i>APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs</i>)	restricted	streamlined
9478W	LANSOPRAZOLE , lansoprazole 30 mg orally disintegrating tablet, 28 (<i>APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs</i>)	restricted	streamlined
1326T	OMEPRAZOLE , omeprazole 20 mg enteric capsule, 30 (<i>APO-Omeprazole, Maxor, Omeprazole Sandoz, Pemzo, Pharmacor Omeprazole 20, Probitor</i>)	restricted	streamlined
1327W	OMEPRAZOLE , omeprazole 20 mg enteric capsule, 30 (<i>APO-Omeprazole, Maxor, Omeprazole Sandoz, Pemzo, Pharmacor Omeprazole 20, Probitor</i>)	restricted	streamlined
8331L	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>APO-Omeprazole, Chem mart Omeprazole, Meprazol, Omeprazole AN, Omeprazole generichealth, Ozmep, Pharmacor Omeprazole, Terry White Chemists Omeprazole</i>)	restricted	streamlined
8333N	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>APO-Omeprazole, Chem mart Omeprazole, Meprazol, Omeprazole AN, Omeprazole generichealth, Ozmep, Pharmacor Omeprazole, Terry White Chemists Omeprazole</i>)	restricted	streamlined

9109K	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>Acimax Tablets, Losec Tablets, Omepral, Omeprazole Sandoz</i>)	restricted	streamlined
9110L	OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30 (<i>Acimax Tablets, Losec Tablets, Omepral, Omeprazole Sandoz</i>)	restricted	streamlined
9423Y	PANTOPRAZOLE , pantoprazole 40 mg enteric coated granules, 30 sachets (<i>Somac</i>)	restricted	streamlined
9424B	PANTOPRAZOLE , pantoprazole 40 mg enteric coated granules, 30 sachets (<i>Somac</i>)	restricted	streamlined
8007K	PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30 (<i>APO-Pantoprazole, APOTEX-Pantoprazole, I-Pantoprazole, Ozpan, Panthron, Panto, Pantoprazole AN, Pantoprazole APOTEX, Pantoprazole Actavis, Pantoprazole GH, Pantoprazole Sandoz, Pantoprazole generichealth, Salpraz, Somac, Sozol</i>)	restricted	streamlined
8008L	PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30 (<i>APO-Pantoprazole, APOTEX-Pantoprazole, I-Pantoprazole, Ozpan, Panthron, Panto, Pantoprazole AN, Pantoprazole APOTEX, Pantoprazole Actavis, Pantoprazole GH, Pantoprazole Sandoz, Pantoprazole generichealth, Salpraz, Somac, Sozol</i>)	restricted	streamlined
8508T	RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30 (<i>APO-Rabeprazole, Chem mart Rabeprazole, Parbezol, Pariet, Parzol 20, Rabeprazole AN, Rabeprazole SUN, Rabeprazole Sandoz, Rabeprazole-DRLA, Terry White Chemists Rabeprazole, Zabep</i>)	restricted	streamlined
8509W	RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30 (<i>APO-Rabeprazole, Chem mart Rabeprazole, Parbezol, Pariet, Parzol 20, Rabeprazole AN, Rabeprazole SUN, Rabeprazole Sandoz, Rabeprazole-DRLA, Terry White Chemists Rabeprazole, Zabep</i>)	restricted	streamlined

Alteration – Number of Repeats

		From	To
9423Y	PANTOPRAZOLE , pantoprazole 40 mg enteric coated granules, 30 sachets (<i>Somac</i>)	2	1
8007K	PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30 (<i>APO-Pantoprazole, APOTEX-Pantoprazole, I-Pantoprazole, Ozpan, Panthron, Panto, Pantoprazole AN, Pantoprazole APOTEX, Pantoprazole Actavis, Pantoprazole GH, Pantoprazole Sandoz, Pantoprazole generichealth, Salpraz, Somac, Sozol</i>)	2	1
8509W	RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30 (<i>APO-Rabeprazole, Chem mart Rabeprazole, Parbezol, Pariet, Parzol 20, Rabeprazole AN, Rabeprazole SUN, Rabeprazole Sandoz, Rabeprazole-DRLA, Terry White Chemists Rabeprazole, Zabep</i>)	2	1

Advance Notices

1 June 2019

Deletion – Brand

2518M	<i>Emend, MK</i> – APREPITANT , aprepitant 165 mg capsule, 1
1147J	<i>Zedace, AF</i> – CAPTOPRIL , captopril 12.5 mg tablet, 90
1208N	<i>Ciproxin 250, BN</i> – CIPROFLOXACIN , ciprofloxacin 250 mg tablet, 14
3138E	<i>Clindamycin-Link, LI</i> – CLINDAMYCIN , clindamycin 150 mg capsule, 24
5057E	<i>Clindamycin-Link, LI</i> – CLINDAMYCIN , clindamycin 150 mg capsule, 24
1269T	<i>Cyprone, AF</i> – CYPROTERONE , cyproterone acetate 50 mg tablet, 20
1270W	<i>Cyprone, AF</i> – CYPROTERONE , cyproterone acetate 50 mg tablet, 50
9164H	<i>Cystine 500, VF</i> – CYSTINE WITH CARBOHYDRATE , cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets
8389M	<i>Nupentin Tabs, AF</i> – GABAPENTIN , gabapentin 800 mg tablet, 100
8559L	<i>Nupentin Tabs, AF</i> – GABAPENTIN , gabapentin 600 mg tablet, 100
1280J	<i>Hydrene 25/50, AF</i> – HYDROCHLOROTHIAZIDE + TRIAMTERENE , hydrochlorothiazide 25 mg + triamterene 50 mg tablet, 100
5132D	<i>Dilaudid, MF</i> – HYDROMORPHONE , hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL
8424J	<i>Dilaudid, MF</i> – HYDROMORPHONE , hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL
8534E	<i>Zircol, AF</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
8679T	<i>Zircol, AF</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28

1966L	<i>Daraprim, RW</i> – PYRIMETHAMINE , pyrimethamine 25 mg tablet, 50
10062N	<i>Orion Temozolomide, ON</i> – TEMOZOLOMIDE , temozolomide 180 mg capsule, 5
2438H	<i>Orion Temozolomide, ON</i> – TEMOZOLOMIDE , temozolomide 180 mg capsule, 5
8378Y	<i>Orion Temozolomide, ON</i> – TEMOZOLOMIDE , temozolomide 5 mg capsule, 5
8379B	<i>Orion Temozolomide, ON</i> – TEMOZOLOMIDE , temozolomide 20 mg capsule, 5
8380C	<i>Orion Temozolomide, ON</i> – TEMOZOLOMIDE , temozolomide 100 mg capsule, 5
8381D	<i>Orion Temozolomide, ON</i> – TEMOZOLOMIDE , temozolomide 250 mg capsule, 5
8819E	<i>Orion Temozolomide, ON</i> – TEMOZOLOMIDE , temozolomide 5 mg capsule, 5
8820F	<i>Orion Temozolomide, ON</i> – TEMOZOLOMIDE , temozolomide 20 mg capsule, 5
8821G	<i>Orion Temozolomide, ON</i> – TEMOZOLOMIDE , temozolomide 100 mg capsule, 5
9361Q	<i>Orion Temozolomide, ON</i> – TEMOZOLOMIDE , temozolomide 140 mg capsule, 5
9362R	<i>Orion Temozolomide, ON</i> – TEMOZOLOMIDE , temozolomide 140 mg capsule, 5
8523N	<i>Tramedo SR 100, AF</i> – TRAMADOL , tramadol hydrochloride 100 mg modified release tablet, 20
8524P	<i>Tramedo SR 150, AF</i> – TRAMADOL , tramadol hydrochloride 150 mg modified release tablet, 20
8525Q	<i>Tramedo SR 200, AF</i> – TRAMADOL , tramadol hydrochloride 200 mg modified release tablet, 20

1 July 2019

Deletion – Brand

8048N	<i>ReoPro, JC</i> – ABCIXIMAB , abciximab 10 mg/5 mL injection, 5 mL vial
2738D	<i>XP Maxamaid, SB</i> – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE , amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g
1204J	<i>Flucon, NV</i> – FLUOROMETHOLONE , fluorometholone 0.1% eye drops, 5 mL
5513E	<i>Flucon, NV</i> – FLUOROMETHOLONE , fluorometholone 0.1% eye drops, 5 mL
8726G	<i>Copaxone, TB</i> – GLATIRAMER ACETATE , glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes
9059T	<i>Avandamet, GK</i> – ROSIGLITAZONE + METFORMIN , rosiglitazone 2 mg + metformin hydrochloride 500 mg tablet, 56
9060W	<i>Avandamet, GK</i> – ROSIGLITAZONE + METFORMIN , rosiglitazone 2 mg + metformin hydrochloride 1 g tablet, 56
9061X	<i>Avandamet, GK</i> – ROSIGLITAZONE + METFORMIN , rosiglitazone 4 mg + metformin hydrochloride 500 mg tablet, 56
9062Y	<i>Avandamet, GK</i> – ROSIGLITAZONE + METFORMIN , rosiglitazone 4 mg + metformin hydrochloride 1 g tablet, 56

1 August 2019

Deletion – Brand

2946C	<i>Phosphate Sandoz, FF</i> – PHOSPHORUS , phosphorus 500 mg effervescent tablet, 100
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1 September 2019

Deletion – Brand

1923F	<i>MMA/PA cooler 15, VF</i> – 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
1711C	<i>Hypurin Isophane, AS</i> – INSULIN ISOPHANE BOVINE , insulin isophane bovine 100 units/mL injection, 1 x 10 mL vial
1713E	<i>Hypurin Neutral, AS</i> – INSULIN NEUTRAL BOVINE , insulin neutral bovine 100 units/mL injection, 1 x 10 mL vial

1 October 2019

Deletion – Brand

2544X	<i>Akineton, GH</i> – BIPERIDEN , biperiden hydrochloride 2 mg tablet, 100
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1 December 2019

Deletion – Brand

1002R Zovirax, GK – **ACICLOVIR**, aciclovir 3% eye ointment, 4.5 g

5501M Zovirax, GK – **ACICLOVIR**, aciclovir 3% eye ointment, 4.5 g

1 January 2020

Deletion – Brand

8362D Capecitabine Apotex, TX – **CAPECITABINE**, capecitabine 500 mg tablet, 120

Palliative Care

Alterations

Alteration – Item Description

From

10127B **MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE**, macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL (*Movicol Liquid*)

To

10127B **MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE**, 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 (*Movicol Liquid*)

From

5389P **MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE**, macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets (*APO-MACROGOL plus ELECTROLYTES*, *Chemists' Own Macrogol with Electrolytes*, *LaxaCon*, *Macrovic*, *Molaxole*, *Movicol*, *lax-sachets*)

To

5389P **MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE**, 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 (*APO-MACROGOL plus ELECTROLYTES*, *Chemists' Own Macrogol with Electrolytes*, *LaxaCon*, *Macrovic*, *Molaxole*, *Movicol*, *lax-sachets*)

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

11688E **APOMORPHINE**, apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges (*Apomine Intermittent*)

Addition – Equivalence Indicator

11475Y *Movapo Pen*, TD – **APOMORPHINE**, apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices

Addition – Note

11475Y **APOMORPHINE**, apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices (*Movapo Pen*)

10057H **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra*, *Remicade*, *Renflexis*)

11396T **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra*, *Renflexis*)

11432Q **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra*, *Renflexis*)

11450P **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra*, *Renflexis*)

11483J **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra*, *Renflexis*)

11488P **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra*, *Renflexis*)

11515C **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra*, *Renflexis*)

Deletions

Deletion – Item

6152T	CLARITHROMYCIN , clarithromycin 500 mg tablet, 100 (<i>APO-Clarithromycin</i>)
11236J	DEFERASIROX , deferasirox 125 mg dispersible tablet, 28 (<i>Exjade</i>)
11241P	DEFERASIROX , deferasirox 125 mg dispersible tablet, 28 (<i>Exjade</i>)
6499C	DEFERASIROX , deferasirox 125 mg dispersible tablet, 28 (<i>Exjade</i>)
11238L	DEFERASIROX , deferasirox 250 mg dispersible tablet, 28 (<i>Exjade</i>)
11244T	DEFERASIROX , deferasirox 250 mg dispersible tablet, 28 (<i>Exjade</i>)
6500D	DEFERASIROX , deferasirox 250 mg dispersible tablet, 28 (<i>Exjade</i>)
11232E	DEFERASIROX , deferasirox 500 mg dispersible tablet, 28 (<i>Exjade</i>)
11243R	DEFERASIROX , deferasirox 500 mg dispersible tablet, 28 (<i>Exjade</i>)
9600G	DEFERASIROX , deferasirox 500 mg dispersible tablet, 28 (<i>Exjade</i>)

Alterations

Alteration – Item Description

From

9680L **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (*Humira*)

To

9680L **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Humira*)

Alteration – Note

11590B	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Remicade</i>)
11595G	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra</i> , <i>Renflexis</i>)
9617E	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra</i> , <i>Remicade</i> , <i>Renflexis</i>)

Alteration – Restriction

11590B	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Remicade</i>)
11595G	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra</i> , <i>Renflexis</i>)
9617E	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra</i> , <i>Remicade</i> , <i>Renflexis</i>)

Alteration – Manufacturer Code

6136Y	<i>Cymevene</i> – GANCICLOVIR , ganciclovir 500 mg injection, 5 vials	From RO	To PB
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Advance Notices

1 June 2019

Deletion – Brand

1082Y	<i>TevaGrastim</i> , TB – FILGRASTIM , filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes
1113N	<i>TevaGrastim</i> , TB – FILGRASTIM , filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

11672H	APOMORPHINE , apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges (<i>Apomine Intermittent</i>)
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Addition – Equivalence Indicator

11477C	<i>Movapo Pen</i> , TD – APOMORPHINE , apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices
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Addition – Note

11477C	APOMORPHINE , apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices (<i>Movapo Pen</i>)
10067W	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Remicade, Renflexis</i>)
11400B	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Renflexis</i>)
11423F	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Renflexis</i>)
11449N	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Renflexis</i>)
11459D	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Remicade</i>)
11461F	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Renflexis</i>)
11486M	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Renflexis</i>)
11490R	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Renflexis</i>)
11514B	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Renflexis</i>)

Deletions

Deletion – Item

5624B	CLARITHROMYCIN , clarithromycin 500 mg tablet, 100 (<i>APO-Clarithromycin</i>)
11235H	DEFERASIROX , deferasirox 125 mg dispersible tablet, 28 (<i>Exjade</i>)
11247Y	DEFERASIROX , deferasirox 125 mg dispersible tablet, 28 (<i>Exjade</i>)
5654N	DEFERASIROX , deferasirox 125 mg dispersible tablet, 28 (<i>Exjade</i>)
11239M	DEFERASIROX , deferasirox 250 mg dispersible tablet, 28 (<i>Exjade</i>)
11240N	DEFERASIROX , deferasirox 250 mg dispersible tablet, 28 (<i>Exjade</i>)
5655P	DEFERASIROX , deferasirox 250 mg dispersible tablet, 28 (<i>Exjade</i>)
11231D	DEFERASIROX , deferasirox 500 mg dispersible tablet, 28 (<i>Exjade</i>)
11234G	DEFERASIROX , deferasirox 500 mg dispersible tablet, 28 (<i>Exjade</i>)
5656Q	DEFERASIROX , deferasirox 500 mg dispersible tablet, 28 (<i>Exjade</i>)

Alterations

Alteration – Item Description

From

9663N **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (*Humira*)

To

9663N **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Humira*)

Alteration – Note

11605T	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Renflexis</i>)
11606W	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Remicade</i>)
5758C	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Remicade, Renflexis</i>)

Alteration – Restriction

11459D	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Remicade</i>)
11605T	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Renflexis</i>)
11606W	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Remicade</i>)
5758C	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Remicade, Renflexis</i>)

Alteration – Manufacturer Code

5749N	Cymevene – GANCICLOVIR , ganciclovir 500 mg injection, 5 vials	From RO	To PB
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Advance Notices

1 June 2019

Deletion – Brand

1123D	TevaGrastim, TB – FILGRASTIM , filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes
1126G	TevaGrastim, TB – FILGRASTIM , filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes

Highly Specialised Drugs Program (Community Access)

Alterations

Alteration – Manufacturer Code

		From	To
10328N	Cymevene – GANCICLOVIR , ganciclovir 500 mg injection, 5 vials	RO	PB

Advance Notices

1 July 2019

Deletion – Brand

10300D	Norvir, VE – RITONAVIR , ritonavir 600 mg/7.5 mL oral liquid, 90 mL
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1 January 2020

Deletion – Brand

10357D	Abacavir/Lamivudine 600/300 APOTEX, TX – ABACAVIR + LAMIVUDINE , abacavir 600 mg + lamivudine 300 mg tablet, 30
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Botulinum Toxin Program

Deletions

Deletion – Note

10999X	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)
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Alterations

Alteration – Restriction

10998W	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)
10999X	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)
10981Y	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial (<i>Dysport</i>)
11006G	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial (<i>Dysport</i>)

Repatriation Pharmaceutical Benefits

Deletions

Deletion – Brand

4010C	Sandoz Nail Repair, SZ – AMOROLFINE , amorolfine 5% application, 5 mL
4238C	Fexal, SZ – FEXOFENADINE , fexofenadine hydrochloride 120 mg tablet, 30

Alterations

Alteration – Item Description

From	
4935R	CADEXOMER-IODINE , DRESSING with CADEXOMER IODINE Sheets 5 g (6 cm x 4 cm), 5, 1 (<i>Iodosorb 66051330</i>)
To	
4935R	CADEXOMER-IODINE , cadexomer-iodine 6 cm x 4 cm dressing, 5 x 5 g sheet (<i>Iodosorb 66051330</i>)
From	
4937W	CADEXOMER-IODINE , DRESSING with CADEXOMER IODINE Sheets 17 g (10 cm x 8 cm), 2, 1 (<i>Iodosorb 66051360</i>)
To	
4937W	CADEXOMER-IODINE , cadexomer-iodine 10 cm x 8 cm dressing, 2 x 17 g sheet (<i>Iodosorb 66051360</i>)

<i>From</i> 4768Y	DRESSING GAUZE EYE , dressing gauze eye pad, 12 pads (<i>Curity 4112</i>)
<i>To</i> 4768Y	DRESSING GAUZE , dressing gauze eye pad, 12 pads (<i>Curity 4112</i>)
<i>From</i> 4767X	GAUZE AND COTTON TISSUE COMBINE ROLL , gauze and cotton tissue combine roll 9 cm x 10 m roll: wrapped pack, 1 pack (<i>BSN 2902165</i>)
<i>To</i> 4767X	GAUZE AND COTTON TISSUE COMBINE ROLL , gauze and cotton tissue combine roll 9 cm x 10 m wrapped pack roll, 1 (<i>BSN 2902165</i>)
<i>From</i> 4761N	GAUZE AND COTTON TISSUE COMBINE ROLL , gauze and cotton tissue combine roll 10 cm x 10 m roll: wrapped pack, 1 pack (<i>JJ 12010</i>)
<i>To</i> 4761N	GAUZE AND COTTON TISSUE COMBINE ROLL , gauze and cotton tissue combine roll 10 cm x 10 m wrapped pack roll, 1 (<i>JJ 12010</i>)
<i>From</i> 4789C	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll (<i>Leukosilk 1024</i>)
<i>To</i> 4789C	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll (<i>Leukosilk 1024</i>)
<i>From</i> 4790D	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll (<i>Leukopor 2474</i>)
<i>To</i> 4790D	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll (<i>Leukopor 2474</i>)
<i>From</i> 4788B	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll (<i>Leukoflex 1124</i>)
<i>To</i> 4788B	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll (<i>Leukoflex 1124</i>)

Advance Notices

1 June 2019

Deletion – Brand

4594T	<i>Nupentin Tabs, AF</i> – GABAPENTIN , gabapentin 600 mg tablet, 100
4595W	<i>Nupentin Tabs, AF</i> – GABAPENTIN , gabapentin 800 mg tablet, 100

General Pharmaceutical Benefits

■ 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 pen devices

11684Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	953.47	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) 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: 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.

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- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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:

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 pen devices

11693K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
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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 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

(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).

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	..	1269.60	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	..	1269.60	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) 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).

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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).

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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).

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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	..	1269.60	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	..	1269.60	40.30	Humira [VE]

■ 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	..	63.91	40.30	^a Symbicort Turbuhaler 400/12 [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 No 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 tablet, 30

8601Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	22.05	23.28	^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	25.63	23.28	^a Nexium [AP]	

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	..	22.05	23.28	^a Esomeprazole ACTAVIS [EA]	^a Noxicid Caps [AL]

■ 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 tablet, 30

3401B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.05	23.28	^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	25.63	23.28	^a Nexium [AP]	

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	..	22.05	23.28	^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 capsule, 30

11687D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.64	18.87	^a Esomeprazole ACTAVIS [EA]	^a Noxicid Caps [AL]

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	..	17.64	18.87	^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	21.22	18.87	^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 capsule, 30

10343J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.64	18.87	^a Esomeprazole ACTAVIS [EA]	^a Noxicid Caps [AL]

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	..	17.64	18.87	^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	21.22	18.87	^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.

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 capsule, 30

10295W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	17.64	18.87	^a Esomeprazole ACTAVIS [EA]	^a Noxicid Caps [AL]

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	..	17.64	18.87	^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	21.22	18.87	^a Nexium [AP]	

■ **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.

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	..	1049.54	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	..	1049.54	40.30	Brenzys [MK]

▪ **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.

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	..	*1049.55	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
	1	5	..	1049.54	40.30	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
	1	5	..	1049.54	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.

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; 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 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	..	*1049.55	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	..	1049.54	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	..	1049.54	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 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 patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (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, 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	..	*1049.55	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	..	1049.54	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	..	1049.54	40.30	^a Brenzys [MK]	^a Enbrel [PF]

■ 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
	1	5	..	51.18	40.30	Adenuric [FK]

NP

■ 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	..	3785.66	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 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 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) 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

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:

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	..	3411.04	40.30	Taltz [LY]

■ 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
	1	1	..	50.64	40.30	Vimpat [UC]

lacosamide 50 mg tablet, 14

9333F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	30.98	32.21	Vimpat [UC]

lacosamide 150 mg tablet, 14

9336J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	70.28	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
	4	5	..	*89.93	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
	1	5	..	168.57	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 200 mg tablet, 56

9338L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	330.44	40.30	Vimpat [UC]

lacosamide 150 mg tablet, 56

9337K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	249.09	40.30	Vimpat [UC]

lacosamide 10 mg/mL oral liquid, 200 mL

11694L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±6	5	..	*388.65	40.30	Vimpat [UC]

■ 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
	1	5	..	14.70	15.93	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
	1	5	..	14.47	15.70	^a APO-Lansoprazole ODT [TX]	^a Lansoprazole ODT GH [GQ]
						^a Zopral ODT [AF]	
			^b 4.81	19.28	15.70	^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)

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	..	16.96	18.19	^a APO-Lansoprazole [TX] ^a Zopral [AF]	^a Lanzopran [RA]

▪ **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 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	..	16.96	18.19	^a APO-Lansoprazole ODT [TX] ^a Zopral ODT [AF]	^a Lansoprazole ODT GH [GQ]
			^B 4.81	21.77	18.19	^a Zoton FasTabs [PF]	

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	..	16.96	18.19	^a APO-Lansoprazole [TX] ^a Zopral [AF]	^a Lanzopran [RA]

▪ **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 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	..	16.96	18.19	^a APO-Lansoprazole ODT [TX] ^a Zopral ODT [AF]	^a Lansoprazole ODT GH [GQ]
			^B 4.81	21.77	18.19	^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 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	..	16.96	18.19	^a APO-Lansoprazole ODT [TX] ^a Zopral ODT [AF]	^a Lansoprazole ODT GH [GQ]
			^B 4.81	21.77	18.19	^a Zoton FasTabs [PF]	

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	..	16.96	18.19	^a APO-Lansoprazole [TX] ^a Zopral [AF]	^a Lanzopran [RA]

▪ **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	..	14.95	16.18	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	..	15.76	16.99	^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	..	15.76	16.99	^a APO-Omeprazole [TX] ^a Meprazol [SZ] ^a Omeprazole generichealth [GQ] ^a Pharmacor Omeprazole [CR]	^a Chem mart Omeprazole [CH] ^a Omeprazole AN [EA] ^a Ozmepr [ZP] ^a Terry White Chemists Omeprazole [TW]

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	..	15.76	16.99	^a Acimax Tablets [AL] ^a Omeprazole Sandoz [SZ]	^a Omepral [ZA]
			^B 7.36	23.12	16.99	^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	..	15.76	16.99	^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	..	15.76	16.99	^a Acimax Tablets [AL] ^a Omeprazole Sandoz [SZ]	^a Omepral [ZA]
			^B 7.36	23.12	16.99	^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	..	15.76	16.99	^a APO-Omeprazole [TX] ^a Meprazol [SZ] ^a Omeprazole generichealth [GQ] ^a Pharmacor Omeprazole [CR]	^a Chem mart Omeprazole [CH] ^a Omeprazole AN [EA] ^a Ozmepr [ZP] ^a Terry White Chemists Omeprazole [TW]

■ 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	..	15.76	16.99	^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
NP	1	1	..	15.76	16.99	^a APO-Omeprazole [TX] ^a Meprazol [SZ] ^a Omeprazole generichealth [GQ] ^a Pharmacor Omeprazole [CR]	^a Chem mart Omeprazole [CH] ^a Omeprazole AN [EA] ^a Ozmepr [ZP] ^a Terry White Chemists Omeprazole [TW]

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	..	15.76	16.99	^a Acimax Tablets [AL] ^a Omeprazole Sandoz [SZ]	^a Omepral [ZA]
			^b 7.36	23.12	16.99	^a Losec Tablets [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 125 mg capsule, 21

11698Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4238.89	40.30	Ibrance [PF]

palbociclib 75 mg capsule, 21

11699R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4238.89	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	..	4238.89	40.30	Ibrance [PF]

■ **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
	1	5	..	12.58	13.81	^a APO-Pantoprazole [TX] ^a Ozpan [RA] ^a Panto [TK] ^a Pantoprazole AN [EA] ^a Pantoprazole generichealth [HQ] ^a Salpraz [AF] ^a Sozol [RW]	^a APOTEX-Pantoprazole [GX] ^a Panthron [ER] ^a Pantofast 20 [RZ] ^a Pantoprazole APOTEX [TY] ^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.

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
	1	5	..	32.45	33.68	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
	1	5	..	13.88	15.11	^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)

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	..	32.45	33.68	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	..	13.88	15.11	^a APO-Pantoprazole [TX] ^a I-Pantoprazole [CR] ^a Panthron [ER] ^a Pantoprazole Actavis [ED] ^a Pantoprazole generichealth [HQ] ^a Pantoprazole Sandoz [SZ] ^a Somac [NQ]	^a APOTEX-Pantoprazole [GX] ^a Ozpan [RA] ^a Panto [TK] ^a Pantoprazole AN [EA] ^a Pantoprazole GH [GQ] ^a Salpraz [AF] ^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)

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	..	32.45	33.68	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	..	13.88	15.11	^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]

■ 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 cytogenic 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 45 mg tablet, 30

10530F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6479.09	40.30	Iclusig [TS]

ponatinib 15 mg tablet, 60

10520Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5759.65	40.30	Iclusig [TS]

■ 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
	1	5	..	14.37	15.60	^a APO-Rabeprazole [TX]	^a Parbezol [RW]
						^a Parzol 10 [ZP]	^a Rabeprazole AN [EA]
						^a Rabeprazole-DRLA [RZ]	^a Rabeprazole Sandoz [SZ]
						^a Pariet [JC]	
			^b 5.01	19.38	15.60		

■ 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	..	14.37	15.60	^a APO-Rabeprazole [TX] ^a Parbezol [RW] ^a Rabeprazole AN [EA] ^a Rabeprazole Sandoz [SZ] ^a Terry White Chemists Rabeprazole [TW]	^a Chem mart Rabeprazole [CH] ^a Parzol 20 [ZP] ^a Rabeprazole-DRLA [RZ] ^a Rabeprazole SUN [RN] ^a Zabep [AL]
			^b 5.01	19.38	15.60	^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	..	14.37	15.60	^a APO-Rabeprazole [TX] ^a Parbezol [RW] ^a Rabeprazole AN [EA] ^a Rabeprazole Sandoz [SZ] ^a Terry White Chemists Rabeprazole [TW]	^a Chem mart Rabeprazole [CH] ^a Parzol 20 [ZP] ^a Rabeprazole-DRLA [RZ] ^a Rabeprazole SUN [RN] ^a Zabep [AL]
			^b 5.01	19.38	15.60	^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	..	14.37	15.60	^a APO-Rabeprazole [TX] ^a Parbezol [RW] ^a Rabeprazole AN [EA] ^a Rabeprazole Sandoz [SZ] ^a Terry White Chemists Rabeprazole [TW]	^a Chem mart Rabeprazole [CH] ^a Parzol 20 [ZP] ^a Rabeprazole-DRLA [RZ] ^a Rabeprazole SUN [RN] ^a Zabep [AL]
			^b 5.01	19.38	15.60	^a Pariet [JC]	

■ 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	..	1926.62	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	..	5511.05	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	..	3724.38	40.30	Kisqali [NV]

■ 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	..	..	*5311.05	40.30	Kuvan [IO]

■ 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	..	..	*2696.07	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	..	*5311.05	40.30	Kuvan [IO]

■ 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	..	1586.52	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.

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).

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	..	1586.52	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 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 Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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) 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.

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.

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:

(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.

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.

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
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■ 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	..	3261.09	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 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 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].

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	..	3261.09	40.30	Ilumya [RA]

■ 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.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

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 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.

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

The duration of the break in therapy will be measured from the date the last 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.

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.

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.

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.

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 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 biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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 medicine (Initial 2 - Change or Re-commencement of treatment after a break in therapy 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, 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 Initial 3 '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 Initial 3 '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.

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.

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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note No 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 previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

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 provided for all continuing treatment applications.

An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment

course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was issued in this cycle and the date of the first application under a new cycle.

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

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 and Initial 3 (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 psoriatic arthritis.

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 under the Initial 3 (Grandfathered patients) 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 restrictions.

Population criteria:

- Patient must be aged 18 years or older.

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

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (Grandfathered patients)

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 provided for all continuing treatment applications.

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 an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response 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 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

tofacitinib 5 mg tablet, 56

11675L	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1267.64	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.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

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 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.

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

The duration of the break in therapy will be measured from the date the last 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.

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.

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.

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.
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 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 biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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 medicine (Initial 2 - Change or Re-commencement of treatment after a break in therapy 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, 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 Initial 3 '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 Initial 3 '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.

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.

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 treatment application is

submitted within a treatment cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note No 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 or patient recommencing treatment after a break in therapy of 5 years or more)

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 severe active psoriatic arthritis, **AND**
- Patient must not have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition in the previous 5 years, **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; and

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

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 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.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was issued 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 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 therapy 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.

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

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

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).

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.

Assessment of a patient's response to an 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 continuing treatment, must be conducted no later than 1 month from the date of completion of this initial course of treatment.

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

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

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 fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was 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

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after more than 5 years break in therapy) or Initial 2 (change or recommencement of treatment after a break in therapy of less 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 or recommencement of treatment after more than 5 years break in therapy) 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 therapy 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.

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	..	1267.64	40.30	Xeljanz [PF]

■ 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) Commencement 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	..	4348.38	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 medical 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:

- (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.

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 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 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	..	4348.38	40.30	Stelara [JC]

Highly Specialised Drugs Program (Private Hospital)

■ APOMORPHINE

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

Note Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pre-filled syringe and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

Authority required

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices

11475Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	20	5	..	*2767.69	^a Movapo Pen [TD]

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges

11688E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	20	5	..	*2767.69	^a Apomine Intermittent [PF]

■ INFLIXIMAB

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 number of repeats may be authorised.

Authority required

Acute severe ulcerative colitis

Treatment criteria:

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

Clinical criteria:

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

Population criteria:

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

infliximab 100 mg injection, 1 vial

10057H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	473.84	^a Inflectra [PF]	^a Remicade [JC]
					^a Renflexis [MK]	

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term biological medicine appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

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

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised 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 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

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must 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.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

Patients are eligible to receive subsequent 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 of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

infliximab 100 mg injection, 1 vial

11396T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	473.84	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term "biological medicine" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS- subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Re commencement 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 or infliximab therapy 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 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 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

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

infliximab 100 mg injection, 1 vial

11432Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	473.84	^a Inflectra [PF]	^a Renflexis [MK]

▪ **INFLIXIMAB**

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. 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 Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe Crohn disease

Treatment Phase: Subsequent continuing treatment

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.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First Continuing treatment restriction; AND
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND
- Patient must have a total PCDAI score of 30 points or less.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The PCDAI assessment must be no more than 1 month old at the time of application.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

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

infliximab 100 mg injection, 1 vial

11450P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	473.84	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). 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 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

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

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

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

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

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

infliximab 100 mg injection, 1 vial

11483J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	473.84	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab 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 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

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be used to determine response for all subsequent continuing treatments.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

infliximab 100 mg injection, 1 vial

11488P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	473.84	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

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

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

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

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, secukinumab or ustekinumab treatment prior to 1 March 2019 is considered to start their first cycle as of 1 March 2019.

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

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 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 biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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 medicine (Initial 2 - Change or Re-commencement of treatment after a break in therapy 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, golimumab and secukinumab, 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 Initial 3 '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.

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.

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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

either of the following:

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

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

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

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

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

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

infliximab 100 mg injection, 1 vial

11515C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	473.84	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, 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 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

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

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

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Approval will 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

Severe chronic plaque psoriasis

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

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

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

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.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11595G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	473.84	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, 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 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, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

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

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Severe chronic plaque psoriasis

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

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

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

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

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11590B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	473.84	Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, 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.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 - Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 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 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, 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.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note 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 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

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

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, 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 quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

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

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

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

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note 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 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is

submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

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

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the

continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

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

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

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

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

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

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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.

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

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

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

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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).

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).

infliximab 100 mg injection, 1 vial

9617E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	473.84	^a Inflectra [PF] ^a Renflexis [MK]	^a Remicade [JC]

Highly Specialised Drugs Program (Public Hospital)

■ APOMORPHINE

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

Note Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pre-filled syringe and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

4833

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices

11477C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	20	5	..	*2720.40	^a Movapo Pen [TD]

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges

11672H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	20	5	..	*2720.40	^a Apomine Intermittent [PF]

■ INFLIXIMAB

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Authority required (STREAMLINED)

4524

Acute severe ulcerative colitis

Treatment criteria:

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

Clinical criteria:

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

Population criteria:

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

infliximab 100 mg injection, 1 vial

10067W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	1	..	*2243.05	^a Inflectra [PF] ^a Renflexis [MK]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab 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 Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have 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 of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

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

infliximab 100 mg injection, 1 vial

11459D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	448.61	Remicade [JC]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib). 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 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)

8755

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

infliximab 100 mg injection, 1 vial

11490R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*1345.83	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term biological medicine appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one

time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised 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 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)

7763

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated 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.

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

Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

infliximab 100 mg injection, 1 vial

11400B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	2	..	*1794.44	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term "biological medicine" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 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 or infliximab therapy 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 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 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)

7847

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

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.

Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

infliximab 100 mg injection, 1 vial

11423F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	2	..	*1794.44	^a Inflectra [PF]	^a Renflexis [MK]

▪ INFLIXIMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. 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 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)

7931

Moderate to severe Crohn disease

Treatment Phase: Subsequent continuing treatment

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.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First Continuing treatment restriction; AND
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND
- Patient must have a total PCDAI score of 30 points or less.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The PCDAI assessment must be no more than 1 month old at the time of prescribing.

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

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

infliximab 100 mg injection, 1 vial

11449N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	2	..	*1794.44	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab 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 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)

8109

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be used to determine response for all subsequent continuing treatments.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

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

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was issued in this cycle and the date of the first application under a new cycle.

infliximab 100 mg injection, 1 vial

11486M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	3	..	*1794.44	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

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

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

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

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, secukinumab or ustekinumab treatment prior to 1 March 2019 is considered to start their first cycle as of 1 March 2019.

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

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 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 biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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 medicine (Initial 2 - Change or Re-commencement of treatment after a break in therapy 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, golimumab and secukinumab, 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 Initial 3 '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.

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.

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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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)

8199

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

either of the following:

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

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

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

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

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

The measurement of response to the prior course of therapy must 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 in this treatment cycle.

infliximab 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
11514B	4	2	..	*1794.44	^a Inflectra [PF]	^a Renflexis [MK]

INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, 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 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, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

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

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Severe chronic plaque psoriasis

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

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

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

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

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11606W	1	..	..	448.61	Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab 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 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)

7989

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have 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 of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

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

infliximab 100 mg injection, 1 vial

11461F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	2	..	*1794.44	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, 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 Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required (STREAMLINED)

8844

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

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

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required (STREAMLINED)

8940

Severe chronic plaque psoriasis

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

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

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11605T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	2	..	*1794.44	^a Inflectra [PF]	^a Renflexis [MK]

▪ **INFLIXIMAB**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, 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 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 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, 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.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an

application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note 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 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

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

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, 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 quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

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

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

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

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note 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 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

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

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

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

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

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

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

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

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

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

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

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

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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).

infliximab 100 mg injection, 1 vial

5758C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	448.61	^a Inflectra [PF] ^a Renflexis [MK]	^a Remicade [JC]

Botulinum Toxin Program

■ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

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

Authority required (STREAMLINED)

5359

Dynamic equinus foot deformity

Clinical criteria:

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

Population criteria:

- Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)

8822

Dynamic equinus foot deformity

Clinical criteria:

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

botulinum toxin type A 100 units injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10998W	4	..	..	*1397.25	40.30	Botox [AG]

■ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

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

Authority required (STREAMLINED)

5178

Moderate to severe spasticity of the upper limb

Clinical criteria:

- Patient must have cerebral palsy.

Population criteria:

- Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR

- Must be treated by a plastic surgeon.

Authority required (STREAMLINED)

8929

Moderate to severe spasticity of the upper limb

Clinical criteria:

- Patient must have cerebral palsy.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

Authority required (STREAMLINED)

5220

Moderate to severe spasticity of the upper limb following a stroke

Clinical criteria:

- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**
- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

botulinum toxin type A 100 units injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10999X	4	..	..	*1397.25	40.30	Botox [AG]

■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

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

Authority required (STREAMLINED)

5359

Dynamic equinus foot deformity

Clinical criteria:

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

Population criteria:

- Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)

8822

Dynamic equinus foot deformity

Clinical criteria:

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

10981Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1221.85	40.30	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

11006G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*1094.79	40.30	Dysport [IS]