



Australian Government

**Department of Health
and Aged Care**



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 September 2022



Fees, Patient Contributions and Safety Net Thresholds

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

Dispensing Fees:	Ready-prepared	\$7.82
	Dangerous drug fee	\$4.84
	Extemporaneously-prepared	\$9.86
	Allowable additional patient charge*	\$4.54
Additional Fees (for safety net prices):	Ready-prepared	\$1.31
	Extemporaneously-prepared	\$1.68
Patient Co-payments:	General	\$42.50
	Concessional	\$6.80
Safety Net Thresholds:	General	\$1457.10
	Concessional	\$244.80
Safety Net Card Issue Fee:		\$10.65

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

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 September 2022. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

General Pharmaceutical Benefits

Additions

Addition – Item

13080K	CEFAZOLIN , cefazolin 2 g injection, 5 vials (<i>Cefazolin-AFT</i>)
13097H	CEFAZOLIN , cefazolin 2 g injection, 5 vials (<i>Cefazolin-AFT</i>)
13106T	DAPAGLIFLOZIN , dapagliflozin 10 mg tablet, 28 (<i>Forxiga</i>)
13093D	GILTERITINIB , gilteritinib 40 mg tablet, 84 (<i>Xospata</i>)
13094E	GILTERITINIB , gilteritinib 40 mg tablet, 84 (<i>Xospata</i>)
13110B	GLATIRAMER ACETATE , glatiramer acetate 40 mg/mL injection, 12 x 1 mL pen devices (<i>Copaxone</i>)
13108X	MEDIUM CHAIN TRIGLYCERIDES , medium chain triglycerides oral liquid, 15 x 225 mL bottles (<i>K.Quik</i>)
13079J	NIRAPARIB , niraparib 100 mg capsule, 84 (<i>Zejula</i>)
13089X	NIRAPARIB , niraparib 100 mg capsule, 56 (<i>Zejula</i>)
13092C	NIRAPARIB , niraparib 100 mg capsule, 84 (<i>Zejula</i>)
13112D	NIRAPARIB , niraparib 100 mg capsule, 56 (<i>Zejula</i>)
13098J	OXYBUTYNIN , oxybutynin hydrochloride 5 mg tablet, 100 (<i>Oxybutynin Chloride (Novitium)</i>)
13100L	POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL , polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses (<i>Systane</i>)
13113E	POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL , polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses (<i>Systane</i>)

Addition – Brand

1976B	<i>Fyzant, JU</i> – ICATIBANT , icatibant 30 mg/3 mL injection, 3 mL syringe
11253G	<i>ARX-Sunitinib, XT</i> – SUNITINIB , sunitinib 25 mg capsule, 28
2842N	<i>ARX-Sunitinib, XT</i> – SUNITINIB , sunitinib 25 mg capsule, 28
2959R	<i>ARX-Sunitinib, XT</i> – SUNITINIB , sunitinib 25 mg capsule, 28
9418Q	<i>ARX-Sunitinib, XT</i> – SUNITINIB , sunitinib 25 mg capsule, 28
9421W	<i>ARX-Sunitinib, XT</i> – SUNITINIB , sunitinib 25 mg capsule, 28
9489K	<i>ARX-Sunitinib, XT</i> – SUNITINIB , sunitinib 25 mg capsule, 28
10459L	<i>ARX-Sunitinib, XT</i> – SUNITINIB , sunitinib 37.5 mg capsule, 28
10464R	<i>ARX-Sunitinib, XT</i> – SUNITINIB , sunitinib 37.5 mg capsule, 28
10473F	<i>ARX-Sunitinib, XT</i> – SUNITINIB , sunitinib 37.5 mg capsule, 28
10503T	<i>ARX-Sunitinib, XT</i> – SUNITINIB , sunitinib 37.5 mg capsule, 28
10504W	<i>ARX-Sunitinib, XT</i> – SUNITINIB , sunitinib 37.5 mg capsule, 28
11256K	<i>ARX-Sunitinib, XT</i> – SUNITINIB , sunitinib 37.5 mg capsule, 28

10010W	ARX-Sunitinib, XT – SUNITINIB , sunitinib 50 mg capsule, 28
11250D	ARX-Sunitinib, XT – SUNITINIB , sunitinib 50 mg capsule, 28
2837H	ARX-Sunitinib, XT – SUNITINIB , sunitinib 50 mg capsule, 28
9419R	ARX-Sunitinib, XT – SUNITINIB , sunitinib 50 mg capsule, 28
9422X	ARX-Sunitinib, XT – SUNITINIB , sunitinib 50 mg capsule, 28
9490L	ARX-Sunitinib, XT – SUNITINIB , sunitinib 50 mg capsule, 28

Addition – Equivalence Indicator

1976B	Cipla Icatibant, LR – ICATIBANT , icatibant 30 mg/3 mL injection, 3 mL syringe
8039D	Ditropan, SW – OXYBUTYNIN , oxybutynin hydrochloride 5 mg tablet, 100

Addition – Note

10416F	GLATIRAMER ACETATE , glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes (<i>Copaxone</i> , GLATIRAMER ACETATE-TEVA , <i>Glatira</i>)
11444H	MEDIUM CHAIN TRIGLYCERIDES , medium chain triglycerides oral liquid, 15 x 225 mL bottles (<i>Betaquik</i>)
12170M	OLAPARIB , olaparib 100 mg tablet, 56 (<i>Lynparza</i>)
12157W	OLAPARIB , olaparib 150 mg tablet, 56 (<i>Lynparza</i>)
8039D	OXYBUTYNIN , oxybutynin hydrochloride 5 mg tablet, 100 (<i>Ditropan</i>)

Deletions

Deletion – Item

8683B	EPTIFIBATIDE , eptifibatide 20 mg/10 mL injection, 10 mL vial (<i>Integrilin</i>)
8684C	EPTIFIBATIDE , eptifibatide 75 mg/100 mL injection, 100 mL vial (<i>Integrilin</i>)
11624T	VENETOCLAX , venetoclax 10 mg tablet, 14 (<i>Venclexta</i>)

Deletion – Brand

8451T	<i>Dimirel</i> , AV – GLIMEPIRIDE , glimepiride 2 mg tablet, 30
5450W	<i>Arabloc</i> , AV – LEFLUNOMIDE , leflunomide 20 mg tablet, 30
8375T	<i>Arabloc</i> , AV – LEFLUNOMIDE , leflunomide 20 mg tablet, 30

Deletion – Equivalence Indicator

12999E	<i>Venclexta</i> , VE – VENETOCLAX , venetoclax 10 mg tablet, 2
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Deletion – Note

12613W	ALIROCUMAB , alirocumab 75 mg/mL injection, 2 x 1 mL pen devices (<i>Praluent</i>)
12604J	ALIROCUMAB , alirocumab 150 mg/mL injection, 2 x 1 mL pen devices (<i>Praluent</i>)
11266Y	SUNITINIB , sunitinib 12.5 mg capsule, 28 (<i>Sunitinib Sandoz</i> , <i>Sutent</i>)
11253G	SUNITINIB , sunitinib 25 mg capsule, 28 (<i>ARX-Sunitinib</i> , <i>Sunitinib Sandoz</i> , <i>Sutent</i>)
11256K	SUNITINIB , sunitinib 37.5 mg capsule, 28 (<i>ARX-Sunitinib</i> , <i>Sunitinib Sandoz</i> , <i>Sutent</i>)
11250D	SUNITINIB , sunitinib 50 mg capsule, 28 (<i>ARX-Sunitinib</i> , <i>Sunitinib Sandoz</i> , <i>Sutent</i>)
12639F	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)
12654B	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)
12999E	VENETOCLAX , venetoclax 10 mg tablet, 2 (<i>Venclexta</i>)

Deletion – Restriction

12613W	ALIROCUMAB , alirocumab 75 mg/mL injection, 2 x 1 mL pen devices (<i>Praluent</i>)
12604J	ALIROCUMAB , alirocumab 150 mg/mL injection, 2 x 1 mL pen devices (<i>Praluent</i>)
12639F	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)
12654B	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)

Alterations

Alteration – Note

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>)
1220F	ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL syringes (<i>Orencia</i>)
1221G	ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL syringes (<i>Orencia</i>)
13034B	ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL pen devices (<i>Orencia Clickject (Germany)</i>)
13037E	ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL pen devices (<i>Orencia Clickject (Germany)</i>)
12390D	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira</i>)
12400P	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira</i>)
12429E	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira</i>)
12430F	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira</i>)
12326R	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
12329X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
8737W	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
8741C	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
9099X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
9100Y	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
11437Y	BARICITINIB , baricitinib 2 mg tablet, 28 (<i>Olumiant</i>)
11442F	BARICITINIB , baricitinib 2 mg tablet, 28 (<i>Olumiant</i>)
11443G	BARICITINIB , baricitinib 4 mg tablet, 28 (<i>Olumiant</i>)
11447L	BARICITINIB , baricitinib 4 mg tablet, 28 (<i>Olumiant</i>)
12115P	CEFAZOLIN , cefazolin 2 g injection, 10 vials (<i>Cephazolin Alphapharm</i>)
12118T	CEFAZOLIN , cefazolin 2 g injection, 10 vials (<i>Cephazolin Alphapharm</i>)
5479J	CEFAZOLIN , cefazolin 2 g injection, 1 vial (<i>Cephazolin Alphapharm</i>)
9326W	CEFAZOLIN , cefazolin 2 g injection, 1 vial (<i>Cephazolin Alphapharm</i>)
10905Y	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (<i>Cimzia</i>)
3425G	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (<i>Cimzia</i>)
11322X	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (<i>Cimzia</i>)
11325C	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (<i>Cimzia</i>)
10323H	CRIZOTINIB , crizotinib 200 mg capsule, 60 (<i>Xalkori</i>)
11589Y	CRIZOTINIB , crizotinib 200 mg capsule, 60 (<i>Xalkori</i>)
10322G	CRIZOTINIB , crizotinib 250 mg capsule, 60 (<i>Xalkori</i>)
11594F	CRIZOTINIB , crizotinib 250 mg capsule, 60 (<i>Xalkori</i>)
12092K	ENTRECTINIB , entrectinib 200 mg capsule, 90 (<i>Rozlytrek</i>)
11197H	ETANERCEPT , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
8637N	ETANERCEPT , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
8638P	ETANERCEPT , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
11218K	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys</i>)
11220M	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
12838Q	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL cartridges (<i>Enbrel</i>)
12853L	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL cartridges (<i>Enbrel</i>)
12863B	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL cartridges (<i>Enbrel</i>)
9459W	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
9460X	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)

11211C	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i>)
11219L	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
9089J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
9090K	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
11372M	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 0.5 mL pen device (<i>Simponi</i>)
11375Q	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 0.5 mL pen device (<i>Simponi</i>)
3426H	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (<i>Simponi</i>)
3428K	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (<i>Simponi</i>)
12709X	IMATINIB , imatinib 100 mg capsule, 60 (<i>IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
12722N	IMATINIB , imatinib 100 mg capsule, 60 (<i>IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
12723P	IMATINIB , imatinib 400 mg capsule, 30 (<i>IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
12754G	IMATINIB , imatinib 400 mg capsule, 30 (<i>IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i>)
11787J	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9111M	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
11778X	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
9112N	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat, Glivec, IMATINIB RBX, Imatinib-Teva</i>)
12926H	IMATINIB , imatinib 600 mg tablet, 30 (<i>Imatab</i>)
12553Q	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL syringe (<i>Remsuma SC</i>)
12554R	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL pen device (<i>Remsuma SC</i>)
12555T	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL syringe (<i>Remsuma SC</i>)
12566J	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL pen device (<i>Remsuma SC</i>)
12576X	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL syringe (<i>Remsuma SC</i>)
12577Y	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL pen device (<i>Remsuma SC</i>)
10614P	RUXOLITINIB , ruxolitinib 5 mg tablet, 56 (<i>Jakavi</i>)
10616R	RUXOLITINIB , ruxolitinib 5 mg tablet, 56 (<i>Jakavi</i>)
10913J	RUXOLITINIB , ruxolitinib 10 mg tablet, 56 (<i>Jakavi</i>)
10927D	RUXOLITINIB , ruxolitinib 10 mg tablet, 56 (<i>Jakavi</i>)
10615Q	RUXOLITINIB , ruxolitinib 15 mg tablet, 56 (<i>Jakavi</i>)
10619X	RUXOLITINIB , ruxolitinib 15 mg tablet, 56 (<i>Jakavi</i>)
10617T	RUXOLITINIB , ruxolitinib 20 mg tablet, 56 (<i>Jakavi</i>)
10618W	RUXOLITINIB , ruxolitinib 20 mg tablet, 56 (<i>Jakavi</i>)
11304Y	SONIDEGIB , sonidegib 200 mg capsule, 30 (<i>Odomzo</i>)
9488J	SUNITINIB , sunitinib 12.5 mg capsule, 28 (<i>Sunitinib Sandoz, Sutent</i>)
9489K	SUNITINIB , sunitinib 25 mg capsule, 28 (<i>ARX-Sunitinib, Sunitinib Sandoz, Sutent</i>)
10503T	SUNITINIB , sunitinib 37.5 mg capsule, 28 (<i>ARX-Sunitinib, Sunitinib Sandoz, Sutent</i>)
9490L	SUNITINIB , sunitinib 50 mg capsule, 28 (<i>ARX-Sunitinib, Sunitinib Sandoz, Sutent</i>)
10951J	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
10954M	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
11565Q	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
11567T	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
10511F	TOFACITINIB , tofacitinib 5 mg tablet, 56 (<i>Xeljanz</i>)
10517M	TOFACITINIB , tofacitinib 5 mg tablet, 56 (<i>Xeljanz</i>)
11979L	UPADACITINIB , upadacitinib 15 mg modified release tablet, 28 (<i>Rinvoq</i>)
11989B	UPADACITINIB , upadacitinib 15 mg modified release tablet, 28 (<i>Rinvoq</i>)

12620F	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)
12647P	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)
11070P	VISMODEGIB , vismodegib 150 mg capsule, 28 (<i>Erivedge</i>)
11138F	VORINOSTAT , vorinostat 100 mg capsule, 120 (<i>Zolinza</i>)
11141J	VORINOSTAT , vorinostat 100 mg capsule, 120 (<i>Zolinza</i>)
Alteration – Restriction	
12218C	APREMILAST , apremilast 10 mg tablet [4] (&) apremilast 20 mg tablet [4] (&) apremilast 30 mg tablet [19], 27 (<i>Otezla</i>)
12223H	APREMILAST , apremilast 30 mg tablet, 56 (<i>Otezla</i>)
10323H	CRIZOTINIB , crizotinib 200 mg capsule, 60 (<i>Xalkori</i>)
11589Y	CRIZOTINIB , crizotinib 200 mg capsule, 60 (<i>Xalkori</i>)
10322G	CRIZOTINIB , crizotinib 250 mg capsule, 60 (<i>Xalkori</i>)
11594F	CRIZOTINIB , crizotinib 250 mg capsule, 60 (<i>Xalkori</i>)
12092K	ENTRECTINIB , entrectinib 200 mg capsule, 90 (<i>Rozlytrek</i>)
12722N	IMATINIB , imatinib 100 mg capsule, 60 (<i>IMATINIB-DRLA</i> , <i>Imatinib GH</i> , <i>Imatinib-APOTEX</i>)
12723P	IMATINIB , imatinib 400 mg capsule, 30 (<i>IMATINIB-DRLA</i> , <i>Imatinib GH</i> , <i>Imatinib-APOTEX</i>)
11787J	IMATINIB , imatinib 100 mg tablet, 60 (<i>Gilmat</i> , <i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
11778X	IMATINIB , imatinib 400 mg tablet, 30 (<i>Gilmat</i> , <i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
12919Y	IMATINIB , imatinib 600 mg tablet, 30 (<i>Imatab</i>)
12910L	MOLNUPIRAVIR , molnupiravir 200 mg capsule, 40 (<i>Lagevrio</i>)
12996B	NIRMATRELVIR (&) RITONAVIR , nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6 (<i>Paxlovid</i>)
12170M	OLAPARIB , olaparib 100 mg tablet, 56 (<i>Lynparza</i>)
12157W	OLAPARIB , olaparib 150 mg tablet, 56 (<i>Lynparza</i>)
10614P	RUXOLITINIB , ruxolitinib 5 mg tablet, 56 (<i>Jakavi</i>)
10616R	RUXOLITINIB , ruxolitinib 5 mg tablet, 56 (<i>Jakavi</i>)
10913J	RUXOLITINIB , ruxolitinib 10 mg tablet, 56 (<i>Jakavi</i>)
10927D	RUXOLITINIB , ruxolitinib 10 mg tablet, 56 (<i>Jakavi</i>)
10615Q	RUXOLITINIB , ruxolitinib 15 mg tablet, 56 (<i>Jakavi</i>)
10619X	RUXOLITINIB , ruxolitinib 15 mg tablet, 56 (<i>Jakavi</i>)
10617T	RUXOLITINIB , ruxolitinib 20 mg tablet, 56 (<i>Jakavi</i>)
10618W	RUXOLITINIB , ruxolitinib 20 mg tablet, 56 (<i>Jakavi</i>)
11304Y	SONIDEGIB , sonidegib 200 mg capsule, 30 (<i>Odomzo</i>)
11266Y	SUNITINIB , sunitinib 12.5 mg capsule, 28 (<i>Sunitinib Sandoz</i> , <i>Sutent</i>)
9488J	SUNITINIB , sunitinib 12.5 mg capsule, 28 (<i>Sunitinib Sandoz</i> , <i>Sutent</i>)
11253G	SUNITINIB , sunitinib 25 mg capsule, 28 (<i>ARX-Sunitinib</i> , <i>Sunitinib Sandoz</i> , <i>Sutent</i>)
9489K	SUNITINIB , sunitinib 25 mg capsule, 28 (<i>ARX-Sunitinib</i> , <i>Sunitinib Sandoz</i> , <i>Sutent</i>)
10503T	SUNITINIB , sunitinib 37.5 mg capsule, 28 (<i>ARX-Sunitinib</i> , <i>Sunitinib Sandoz</i> , <i>Sutent</i>)
11256K	SUNITINIB , sunitinib 37.5 mg capsule, 28 (<i>ARX-Sunitinib</i> , <i>Sunitinib Sandoz</i> , <i>Sutent</i>)
11250D	SUNITINIB , sunitinib 50 mg capsule, 28 (<i>ARX-Sunitinib</i> , <i>Sunitinib Sandoz</i> , <i>Sutent</i>)
9490L	SUNITINIB , sunitinib 50 mg capsule, 28 (<i>ARX-Sunitinib</i> , <i>Sunitinib Sandoz</i> , <i>Sutent</i>)
12620F	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)
12647P	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)
11070P	VISMODEGIB , vismodegib 150 mg capsule, 28 (<i>Erivedge</i>)
11138F	VORINOSTAT , vorinostat 100 mg capsule, 120 (<i>Zolinza</i>)

11141J **VORINOSTAT**, vorinostat 100 mg capsule, 120 (*Zolinza*)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
12332C	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT
12350B	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT
12351C	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT
12354F	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT
12357J	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT
12436M	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT
12440R	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT
10399H	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
10400J	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
10412B	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
10413C	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
10419J	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
10420K	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
10944B	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
10955N	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
10960W	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
10961X	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12325Q	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12326R	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12327T	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12328W	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12329X	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12330Y	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12331B	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12333D	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12334E	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12352D	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12353E	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12356H	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12365T	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12366W	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12367X	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12369B	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12370C	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12385W	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12386X	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12387Y	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12388B	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12401Q	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12402R	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12403T	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT

12415K	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12416L	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12420Q	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12434K	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12437N	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12438P	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12690X	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12719K	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12729Y	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12741N	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
5281Y	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
5282B	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
5283C	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
5284D	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
8737W	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
8741C	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
8963R	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
8964T	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
8965W	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
8966X	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
9033K	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
9034L	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
9077R	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
9078T	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
9099X	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
9100Y	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
9101B	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
9102C	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
9103D	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
9104E	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
9188N	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
9189P	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
9190Q	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
9191R	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
9425C	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
9426D	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
9427E	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
9428F	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
9302N	<i>ARDIX GLICLAZIDE 60mg MR</i> – GLICLAZIDE , gliclazide 60 mg modified release tablet, 60	RX	XT
3093T	<i>Hydrea</i> – HYDROXYCARBAMIDE (HYDROXYUREA) , hydroxycarbamide (hydroxyurea) 500 mg capsule, 100	BQ	LM

Supply Only

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Supply Only Commencing 1 September 2022

3179H **NORETHISTERONE + MESTRANOL**, norethisterone 1 mg + mestranol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28 (*Norinyl-1/28*)

Advance Notices

1 October 2022

Deletion – Brand

8213G **ATOMED, DZ – ATORVASTATIN**, atorvastatin 10 mg tablet, 30
8214H **ATOMED, DZ – ATORVASTATIN**, atorvastatin 20 mg tablet, 30
8215J **ATOMED, DZ – ATORVASTATIN**, atorvastatin 40 mg tablet, 30
8521L **ATOMED, DZ – ATORVASTATIN**, atorvastatin 80 mg tablet, 30
9230T **ATOMED, DZ – ATORVASTATIN**, atorvastatin 10 mg tablet, 30
9231W **ATOMED, DZ – ATORVASTATIN**, atorvastatin 20 mg tablet, 30
9232X **ATOMED, DZ – ATORVASTATIN**, atorvastatin 40 mg tablet, 30
9233Y **ATOMED, DZ – ATORVASTATIN**, atorvastatin 80 mg tablet, 30
11148R **Pregnyl, OQ – HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack
1636D **Metronide 200, AV – METRONIDAZOLE**, metronidazole 200 mg tablet, 21
3339R **Metronide 200, AV – METRONIDAZOLE**, metronidazole 200 mg tablet, 21

1 November 2022

Deletion – Brand

11444H **Betaquik, VF – MEDIUM CHAIN TRIGLYCERIDES**, medium chain triglycerides oral liquid, 15 x 225 mL bottles
8648E **Pacrolim, AF – TACROLIMUS**, tacrolimus 5 mg capsule, 50
10375C **Nutrini Peptisorb, SB – TRIGLYCERIDES MEDIUM CHAIN FORMULA**, triglycerides medium chain formula oral liquid, 8 x 500 mL pouches

1 August 2023

Deletion – Brand

2418G **Amitriptyline Alphapharm 25, MQ – AMITRIPTYLINE**, amitriptyline hydrochloride 25 mg tablet, 50
1358L **Dosulepin Mylan, MQ – DOSULEPIN (DOTHIEPIN)**, dosulepin (dothiepin) hydrochloride 75 mg tablet, 30
1500Y **Hydrocortisone Mylan 20, MQ – HYDROCORTISONE**, hydrocortisone 20 mg tablet, 60

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

13091B **NUSINERSEN**, nusinersen 12 mg/5 mL injection, 5 mL vial (*Spinraza*)
13111C **NUSINERSEN**, nusinersen 12 mg/5 mL injection, 5 mL vial (*Spinraza*)
13096G **RITUXIMAB**, rituximab 100 mg/10 mL injection, 2 x 10 mL vials (*Riximyo, Truxima*)
13109Y **RITUXIMAB**, rituximab 100 mg/10 mL injection, 10 mL vial (*Ruxience*)
13095F **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial (*Riximyo, Ruxience, Truxima*)
13099K **SELINEXOR**, selinexor 20 mg tablet, 16 (*Xpovio*)
13103P **SELINEXOR**, selinexor 20 mg tablet, 20 (*Xpovio*)
13105R **SELINEXOR**, selinexor 20 mg tablet, 32 (*Xpovio*)

Addition – Caution

9642L **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 (*Revlimid*)
9643M **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 (*Revlimid*)

9644N **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 (*Revlimid*)
9645P **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 (*Revlimid*)

Deletions

Deletion – Item

10583B **RITUXIMAB**, rituximab 100 mg/10 mL injection, 2 x 10 mL vials (*Riximyo, Truxima*)
11810N **RITUXIMAB**, rituximab 100 mg/10 mL injection, 2 x 10 mL vials (*Riximyo, Truxima*)
12998D **RITUXIMAB**, rituximab 100 mg/10 mL injection, 10 mL vial (*Ruxience*)
13000F **RITUXIMAB**, rituximab 100 mg/10 mL injection, 10 mL vial (*Ruxience*)
10576P **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial (*Riximyo, Ruxience, Truxima*)
11804G **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial (*Riximyo, Ruxience, Truxima*)
12721M **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial (*Riximyo, Ruxience, Truxima*)
9611W **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial (*Riximyo, Ruxience, Truxima*)

Deletion – Note

12610Q **RISDIPLAM**, risdiplam 750 microgram/mL powder for oral liquid, 80 mL (*Evrysdi*)

Deletion – Restriction

12610Q **RISDIPLAM**, risdiplam 750 microgram/mL powder for oral liquid, 80 mL (*Evrysdi*)

Alterations

Alteration – Note

9621J **ABATACEPT**, abatacept 250 mg injection, 1 vial (*Orencia*)
11483J **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Renflexis*)
11487N **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Remicade, Renflexis*)
6397Q **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Remicade, Renflexis*)
11036W **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 (*Revlimid*)
11966T **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28 (*Revlimid*)
12038N **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 (*Revlimid*)
12058P **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14 (*Revlimid*)
12071H **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 (*Revlimid*)
9642L **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 (*Revlimid*)
11063G **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 (*Revlimid*)
11969Y **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28 (*Revlimid*)
12004T **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14 (*Revlimid*)
12050F **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 (*Revlimid*)
12060R **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 (*Revlimid*)
9643M **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 (*Revlimid*)
11042E **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 (*Revlimid*)
11965R **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28 (*Revlimid*)
12011E **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 (*Revlimid*)
12020P **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 (*Revlimid*)
12069F **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14 (*Revlimid*)
9644N **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 (*Revlimid*)
11055W **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 (*Revlimid*)
12018M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14 (*Revlimid*)
12037M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 (*Revlimid*)
12068E **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 (*Revlimid*)

9645P	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
13045N	NUSINERSEN , nusinersen 12 mg/5 mL injection, 5 mL vial (<i>Spinraza</i>)
10417G	POMALIDOMIDE , pomalidomide 3 mg capsule, 21 (<i>Pomalyst</i>)
12668R	POMALIDOMIDE , pomalidomide 3 mg capsule, 14 (<i>Pomalyst</i>)
10386P	POMALIDOMIDE , pomalidomide 4 mg capsule, 21 (<i>Pomalyst</i>)
12661J	POMALIDOMIDE , pomalidomide 4 mg capsule, 14 (<i>Pomalyst</i>)
9671B	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
9672C	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
9673D	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)

Alteration – Restriction

6232B	CICLOSPORIN , ciclosporin 10 mg capsule, 60 (<i>Neoral 10</i>)
6352H	CICLOSPORIN , ciclosporin 25 mg capsule, 30 (<i>APO-Ciclosporin, Cyclosporin Sandoz, Neoral 25</i>)
6353J	CICLOSPORIN , ciclosporin 50 mg capsule, 30 (<i>APO-Ciclosporin, Cyclosporin Sandoz, Neoral 50</i>)
6354K	CICLOSPORIN , ciclosporin 100 mg capsule, 30 (<i>APO-Ciclosporin, Cyclosporin Sandoz, Neoral 100</i>)
6125J	CICLOSPORIN , ciclosporin 100 mg/mL oral liquid, 50 mL (<i>Neoral</i>)
11036W	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Revlimid</i>)
11966T	LENALIDOMIDE , lenalidomide 5 mg capsule, 28 (<i>Revlimid</i>)
12038N	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Revlimid</i>)
12058P	LENALIDOMIDE , lenalidomide 5 mg capsule, 14 (<i>Revlimid</i>)
12071H	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Revlimid</i>)
9642L	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Revlimid</i>)
11063G	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Revlimid</i>)
11969Y	LENALIDOMIDE , lenalidomide 10 mg capsule, 28 (<i>Revlimid</i>)
12004T	LENALIDOMIDE , lenalidomide 10 mg capsule, 14 (<i>Revlimid</i>)
12050F	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Revlimid</i>)
12060R	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Revlimid</i>)
9643M	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Revlimid</i>)
11042E	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Revlimid</i>)
11965R	LENALIDOMIDE , lenalidomide 15 mg capsule, 28 (<i>Revlimid</i>)
12011E	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Revlimid</i>)
12020P	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Revlimid</i>)
12069F	LENALIDOMIDE , lenalidomide 15 mg capsule, 14 (<i>Revlimid</i>)
9644N	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Revlimid</i>)
11055W	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
12018M	LENALIDOMIDE , lenalidomide 25 mg capsule, 14 (<i>Revlimid</i>)
12037M	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
12068E	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
9645P	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
13045N	NUSINERSEN , nusinersen 12 mg/5 mL injection, 5 mL vial (<i>Spinraza</i>)
13064N	NUSINERSEN , nusinersen 12 mg/5 mL injection, 5 mL vial (<i>Spinraza</i>)
10417G	POMALIDOMIDE , pomalidomide 3 mg capsule, 21 (<i>Pomalyst</i>)
12668R	POMALIDOMIDE , pomalidomide 3 mg capsule, 14 (<i>Pomalyst</i>)
10386P	POMALIDOMIDE , pomalidomide 4 mg capsule, 21 (<i>Pomalyst</i>)
12661J	POMALIDOMIDE , pomalidomide 4 mg capsule, 14 (<i>Pomalyst</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
12349Y	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT
12439Q	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT
12674C	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT
12368Y	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12384T	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12715F	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12731C	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
9679K	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
9680L	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12930M	<i>Sylvant</i> – SILTUXIMAB , siltuximab 100 mg injection, 1 vial	EY	RJ
12934R	<i>Sylvant</i> – SILTUXIMAB , siltuximab 400 mg injection, 1 vial	EY	RJ
9675F	<i>Valcyte</i> – VALGANCICLOVIR , valganciclovir 50 mg/mL powder for oral liquid, 100 mL	RO	PB

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Supply Only Commencing 1 September 2022

11790M **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial (*Riximyo, Ruxience, Truxima*)

Advance Notices

1 November 2022

Deletion – Brand

6217F *Pacrolim, AF* – **TACROLIMUS**, tacrolimus 5 mg capsule, 50

Highly Specialised Drugs Program (Public Hospital)**Additions****Addition – Item**

13083N **NUSINERSEN**, nusinersen 12 mg/5 mL injection, 5 mL vial (*Spinraza*)
13084P **NUSINERSEN**, nusinersen 12 mg/5 mL injection, 5 mL vial (*Spinraza*)
13082M **RITUXIMAB**, rituximab 100 mg/10 mL injection, 2 x 10 mL vials (*Riximyo, Truxima*)
13088W **RITUXIMAB**, rituximab 100 mg/10 mL injection, 10 mL vial (*Ruxience*)
13101M **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial (*Riximyo, Ruxience, Truxima*)
13085Q **SELINEXOR**, selinexor 20 mg tablet, 16 (*Xpovio*)
13086R **SELINEXOR**, selinexor 20 mg tablet, 20 (*Xpovio*)
13104Q **SELINEXOR**, selinexor 20 mg tablet, 32 (*Xpovio*)

Addition – Caution

5783J **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 (*Revlimid*)
5784K **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 (*Revlimid*)
5785L **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 (*Revlimid*)
5786M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 (*Revlimid*)

Deletions**Deletion – Item**

10591K **RITUXIMAB**, rituximab 100 mg/10 mL injection, 2 x 10 mL vials (*Riximyo, Truxima*)

11813R	RITUXIMAB , rituximab 100 mg/10 mL injection, 2 x 10 mL vials (<i>Riximyo, Truxima</i>)
12997C	RITUXIMAB , rituximab 100 mg/10 mL injection, 10 mL vial (<i>Ruxience</i>)
13001G	RITUXIMAB , rituximab 100 mg/10 mL injection, 10 mL vial (<i>Ruxience</i>)
10593M	RITUXIMAB , rituximab 500 mg/50 mL injection, 50 mL vial (<i>Riximyo, Ruxience, Truxima</i>)
11800C	RITUXIMAB , rituximab 500 mg/50 mL injection, 50 mL vial (<i>Riximyo, Ruxience, Truxima</i>)
12739L	RITUXIMAB , rituximab 500 mg/50 mL injection, 50 mL vial (<i>Riximyo, Ruxience, Truxima</i>)
9544H	RITUXIMAB , rituximab 500 mg/50 mL injection, 50 mL vial (<i>Riximyo, Ruxience, Truxima</i>)

Deletion – Note

12614X	RISDIPLAM , risdiplam 750 microgram/mL powder for oral liquid, 80 mL (<i>Evrysdi</i>)
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Deletion – Restriction

12614X	RISDIPLAM , risdiplam 750 microgram/mL powder for oral liquid, 80 mL (<i>Evrysdi</i>)
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Alterations

Alteration – Note

5605B	ABATACEPT , abatacept 250 mg injection, 1 vial (<i>Orencia</i>)
11481G	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Remicade, Renflexis</i>)
11490R	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Renflexis</i>)
5757B	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Remicade, Renflexis</i>)
11029L	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Revlimid</i>)
11967W	LENALIDOMIDE , lenalidomide 5 mg capsule, 28 (<i>Revlimid</i>)
12034J	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Revlimid</i>)
12035K	LENALIDOMIDE , lenalidomide 5 mg capsule, 14 (<i>Revlimid</i>)
12039P	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Revlimid</i>)
5783J	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Revlimid</i>)
11064H	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Revlimid</i>)
11968X	LENALIDOMIDE , lenalidomide 10 mg capsule, 28 (<i>Revlimid</i>)
12057N	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Revlimid</i>)
12061T	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Revlimid</i>)
12070G	LENALIDOMIDE , lenalidomide 10 mg capsule, 14 (<i>Revlimid</i>)
5784K	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Revlimid</i>)
11062F	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Revlimid</i>)
11964Q	LENALIDOMIDE , lenalidomide 15 mg capsule, 28 (<i>Revlimid</i>)
12012F	LENALIDOMIDE , lenalidomide 15 mg capsule, 14 (<i>Revlimid</i>)
12026Y	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Revlimid</i>)
12062W	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Revlimid</i>)
5785L	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Revlimid</i>)
11041D	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
12019N	LENALIDOMIDE , lenalidomide 25 mg capsule, 14 (<i>Revlimid</i>)
12036L	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
12059Q	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
5786M	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
13068T	NUSINERSEN , nusinersen 12 mg/5 mL injection, 5 mL vial (<i>Spinraza</i>)
10406Q	POMALIDOMIDE , pomalidomide 3 mg capsule, 21 (<i>Pomalyst</i>)
12666P	POMALIDOMIDE , pomalidomide 3 mg capsule, 14 (<i>Pomalyst</i>)
10387Q	POMALIDOMIDE , pomalidomide 4 mg capsule, 21 (<i>Pomalyst</i>)

12665N	POMALIDOMIDE , pomalidomide 4 mg capsule, 14 (<i>Pomalyst</i>)
9657G	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
9658H	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
9659J	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)

Alteration – Restriction

5632K	CICLOSPORIN , ciclosporin 10 mg capsule, 60 (<i>Neoral 10</i>)
5634M	CICLOSPORIN , ciclosporin 25 mg capsule, 30 (<i>APO-Ciclosporin, Cyclosporin Sandoz, Neoral 25</i>)
5635N	CICLOSPORIN , ciclosporin 50 mg capsule, 30 (<i>APO-Ciclosporin, Cyclosporin Sandoz, Neoral 50</i>)
5636P	CICLOSPORIN , ciclosporin 100 mg capsule, 30 (<i>APO-Ciclosporin, Cyclosporin Sandoz, Neoral 100</i>)
5633L	CICLOSPORIN , ciclosporin 100 mg/mL oral liquid, 50 mL (<i>Neoral</i>)
11029L	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Revlimid</i>)
11967W	LENALIDOMIDE , lenalidomide 5 mg capsule, 28 (<i>Revlimid</i>)
12034J	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Revlimid</i>)
12035K	LENALIDOMIDE , lenalidomide 5 mg capsule, 14 (<i>Revlimid</i>)
12039P	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Revlimid</i>)
5783J	LENALIDOMIDE , lenalidomide 5 mg capsule, 21 (<i>Revlimid</i>)
11064H	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Revlimid</i>)
11968X	LENALIDOMIDE , lenalidomide 10 mg capsule, 28 (<i>Revlimid</i>)
12057N	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Revlimid</i>)
12061T	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Revlimid</i>)
12070G	LENALIDOMIDE , lenalidomide 10 mg capsule, 14 (<i>Revlimid</i>)
5784K	LENALIDOMIDE , lenalidomide 10 mg capsule, 21 (<i>Revlimid</i>)
11062F	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Revlimid</i>)
11964Q	LENALIDOMIDE , lenalidomide 15 mg capsule, 28 (<i>Revlimid</i>)
12012F	LENALIDOMIDE , lenalidomide 15 mg capsule, 14 (<i>Revlimid</i>)
12026Y	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Revlimid</i>)
12062W	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Revlimid</i>)
5785L	LENALIDOMIDE , lenalidomide 15 mg capsule, 21 (<i>Revlimid</i>)
11041D	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
12019N	LENALIDOMIDE , lenalidomide 25 mg capsule, 14 (<i>Revlimid</i>)
12036L	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
12059Q	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
5786M	LENALIDOMIDE , lenalidomide 25 mg capsule, 21 (<i>Revlimid</i>)
13052Y	NUSINERSEN , nusinersen 12 mg/5 mL injection, 5 mL vial (<i>Spinraza</i>)
13068T	NUSINERSEN , nusinersen 12 mg/5 mL injection, 5 mL vial (<i>Spinraza</i>)
10406Q	POMALIDOMIDE , pomalidomide 3 mg capsule, 21 (<i>Pomalyst</i>)
12666P	POMALIDOMIDE , pomalidomide 3 mg capsule, 14 (<i>Pomalyst</i>)
10387Q	POMALIDOMIDE , pomalidomide 4 mg capsule, 21 (<i>Pomalyst</i>)
12665N	POMALIDOMIDE , pomalidomide 4 mg capsule, 14 (<i>Pomalyst</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
12417M	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT
12435L	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT
12695E	<i>Amgevita</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	TX	XT

12348X	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
12355G	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12698H	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12733E	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
9662M	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	TX	XT
9663N	<i>Amgevita</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	TX	XT
12916T	<i>Sylvant</i> – SILTUXIMAB , siltuximab 100 mg injection, 1 vial	EY	RJ
12922D	<i>Sylvant</i> – SILTUXIMAB , siltuximab 400 mg injection, 1 vial	EY	RJ
9655E	<i>Valcyte</i> – VALGANCICLOVIR , valganciclovir 50 mg/mL powder for oral liquid, 100 mL	RO	PB

Supply Only

From 1 November 2020 when a product is deleted from the Schedule it may now be available under new Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted.

Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written.

Further information on Supply Only arrangements is available at www.pbs.gov.au

Supply Only Commencing 1 September 2022

11805H **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial (*Riximyo*, *Ruxience*, *Truxima*)

Advance Notices

1 November 2022

Deletion – Brand

9561F *Pacrolim*, *AF* – **TACROLIMUS**, tacrolimus 5 mg capsule, 50

Highly Specialised Drugs Program (Community Access)

Alterations

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
10277X	<i>Valcyte</i> – VALGANCICLOVIR , valganciclovir 50 mg/mL powder for oral liquid, 100 mL	RO	PB

IVF Program

Advance Notices

1 October 2022

Deletion – Brand

11154C *Pregnyl*, *OQ* – **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack

11156E *Pregnyl*, *OQ* – **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 5000 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack

Repatriation Pharmaceutical Benefits

Advance Notices

1 October 2022

Deletion – Brand

4343N *Momasone*, *AS* – **MOMETASONE**, mometasone furoate 0.1% ointment, 50 g

4059P *Acris Combi*, *AF* – **RISEDRONATE (&) CALCIUM CARBONATE**, risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28

General Pharmaceutical Benefits

▪ ABATACEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply

treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: 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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

on the Services Australia website at www.servicesaustralia.gov.au
 Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
 Or mailed to:
 Services Australia
 Complex Drugs
 Reply Paid 9826
 HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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

abatacept 125 mg/mL injection, 4 x 1 mL syringes

1221G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	958.88	42.50	Orencia [BQ]

▪ ABATACEPT

Note Pharmaceutical Benefits that have the brand Orencia ClickJect (Germany) may be substituted for Pharmaceutical Benefits that have the brand Orencia ClickJect in the case of a shortage.

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a

different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: 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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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

abatacept 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	..	958.88	42.50	^a Orencia ClickJect [BQ]

abatacept 125 mg/mL injection, 4 x 1 mL pen devices

13034B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2652.91	42.50	^a Orencia Clickject (Germany) [DZ]

▪ ABATACEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at

least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

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

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

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

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 Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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

on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

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

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No 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 requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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

abatacept 125 mg/mL injection, 4 x 1 mL syringes

1220F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	958.88	42.50	Orencia [BQ]

■ ABATACEPT

Note Pharmaceutical Benefits that have the brand Orencia ClickJect (Germany) may be substituted for Pharmaceutical Benefits that have the brand Orencia ClickJect in the case of a shortage.

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

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

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

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

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 Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

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

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

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

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HOBART TAS 7001

Note No 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 requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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

abatacept 125 mg/mL injection, 4 x 1 mL pen devices

11693K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	958.88	42.50	^a Orencia ClickJect [BQ]

abatacept 125 mg/mL injection, 4 x 1 mL pen devices

13037E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2652.91	42.50	^a Orencia Clickject (Germany) [DZ]

▪ **ADALIMUMAB**

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the

next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Authority required (STREAMLINED)

11605

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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.

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.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12329X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	885.56	42.50	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12326R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	885.56	42.50	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ ADALIMUMAB**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

(1) a completed authority prescription form; and

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

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

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

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

(1) a completed authority prescription form; and

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

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

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

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12390D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	885.56	42.50	^a Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9100Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	885.56	42.50	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a

written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

(1) a completed authority prescription form; and

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

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

(1) a completed authority prescription form; and

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

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12430F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	885.56	42.50	^a Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8741C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	885.56	42.50	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological

medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

(1) a completed authority prescription form; and

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

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

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

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

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

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

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

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

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

(1) a completed authority prescription form; and

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

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

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

(1) a completed authority prescription form; and

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

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

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

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

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

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

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12400P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	885.56	42.50	^a Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8737W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	885.56	42.50	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

(1) a completed authority prescription form; and

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

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

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

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

Note Biosimilar prescribing policy

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

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

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

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

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

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

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

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

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

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia

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

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12429E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	885.56	42.50	^a Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9099X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	885.56	42.50	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ APREMILAST

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

13243

Severe chronic plaque psoriasis

Clinical criteria:

- Patient must have failed to achieve an adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR
- Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate, **AND**
- The condition must have caused significant interference with quality of life, **AND**
- Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist; OR
- Must be treated by a general practitioner who has been directed to continue treatment (not initiate treatment) by one of the above practitioner types.

Population criteria:

- Patient must be at least 18 years of age.

apremilast 30 mg tablet, 56

12223H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	652.86	42.50	Otezla [AN]

apremilast 10 mg tablet [4] (&) apremilast 20 mg tablet [4] (&) apremilast 30 mg tablet [19], 27

12218C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	272.35	42.50	Otezla [AN]

■ BARICITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks 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 the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

baricitinib 2 mg tablet, 28

11442F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1271.46	42.50	Olumiant [LY]

baricitinib 4 mg tablet, 28

11443G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1271.46	42.50	Olumiant [LY]

■ BARICITINIB**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat

prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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

baricitinib 2 mg tablet, 28

11437Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1271.46	42.50	Olumiant [LY]

baricitinib 4 mg tablet, 28

11447L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1271.46	42.50	Olumiant [LY]

■ CEFAZOLIN

Note Pharmaceutical benefits that have the form cefazolin 2 g injection, 1 vial, pharmaceutical benefits that have the form cefazolin 2 g injection, 5 vials, and pharmaceutical benefits that have the form cefazolin 2 g injection, 10 vials are equivalent for the purposes of substitution.

Restricted benefit

Cellulitis

cefazolin 2 g injection, 1 vial

5479J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*39.92	41.23	^a Cephazolin Alphapharm [AF]

cefazolin 2 g injection, 10 vials

12115P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	39.99	41.30	^a Cephazolin Alphapharm [AF]

cefazolin 2 g injection, 5 vials

13080K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*39.98	41.29	^a Cefazolin-AFT [AE]

■ CEFAZOLIN

Note Pharmaceutical benefits that have the form cefazolin 2 g injection, 1 vial, pharmaceutical benefits that have the form cefazolin 2 g injection, 5 vials, and pharmaceutical benefits that have the form cefazolin 2 g injection, 10 vials are equivalent for the purposes of substitution.

Note Shared Care Model:

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

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

cefazolin 2 g injection, 1 vial

9326W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	..	..	*39.92	41.23	^a Cephazolin Alphapharm [AF]

cefazolin 2 g injection, 10 vials

12118T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	39.99	41.30	^a Cephazolin Alphapharm [AF]

cefazolin 2 g injection, 5 vials

13097H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*39.98	41.29	^a Cefazolin-AFT [AE]

■ CERTOLIZUMAB PEGOL

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine,

'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

3425G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1025.83	42.50	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11325C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1025.83	42.50	Cimzia [UC]

■ CERTOLIZUMAB PEGOL

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab

course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be

- methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
 - Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
 - Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
 - Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

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

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10905Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3017.69	42.50	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11322X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3017.69	42.50	Cimzia [UC]

■ CRIZOTINIB

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

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

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

- (a) evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

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

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

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

crizotinib 200 mg capsule, 60

10323H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6933.17	42.50	Xalkori [PF]

crizotinib 250 mg capsule, 60

10322G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6933.17	42.50	Xalkori [PF]

■ CRIZOTINIB

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

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

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

- evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

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

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

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

crizotinib 200 mg capsule, 60

11589Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6933.17	42.50	Xalkori [PF]

crizotinib 250 mg capsule, 60

11594F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6933.17	42.50	Xalkori [PF]

■ DAPAGLIFLOZIN**Note Continuing Therapy Only:**

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

Authority required (STREAMLINED)**13230**

Chronic kidney disease

Clinical criteria:

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 25 to 75 mL/min/1.73 m² inclusive prior to initiating treatment with this drug, **AND**
- Patient must have a urinary albumin to creatinine ratio of between 200 to 5000 mg/g (22.6-565 mg/mmol) inclusive prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.

Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.

dapagliflozin 10 mg tablet, 28

13106T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	56.97	42.50	Forxiga [AP]

NP

■ ENTRECTINIB**Note Special Pricing Arrangements apply.****Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

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

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

- evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

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

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

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

entrectinib 200 mg capsule, 90

12092K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7289.58	42.50	Rozlytrek [RO]

■ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to

provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

7276

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11218K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1050.20	42.50	^a Brenzys [RF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11211C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1050.20	42.50	^a Brenzys [RF]

■ ETANERCEPT**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

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

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

11197H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1050.22	42.50	Enbrel [PF]

▪ **ETANERCEPT**

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

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

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

8638P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1050.22	42.50	Enbrel [PF]

■ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL cartridges are equivalent for the purposes of substitution.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

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

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

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

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

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

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

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

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11220M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1050.20	42.50	^a Brenzys [RF]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

11219L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1050.20	42.50	^a Brenzys [RF]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL cartridges

12863B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1050.20	42.50	^a Enbrel [PF]

■ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed,

(c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL cartridges are equivalent for the purposes of substitution.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

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 50 mg/mL injection, 4 x 1 mL pen devices

9460X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1050.20	42.50	^a Brenzys [RF]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9090K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1050.20	42.50	^a Brenzys [RF]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL cartridges

12853L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1050.20	42.50	^a Enbrel [PF]

■ ETANERCEPT**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

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

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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

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

8637N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1050.22	42.50	Enbrel [PF]

■ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine

cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL cartridges are equivalent for the purposes of substitution.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

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

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

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

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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

on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9459W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1050.20	42.50	^a Brenzys [RF]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9089J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1050.20	42.50	^a Brenzys [RF]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL cartridges

12838Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1050.20	42.50	^a Enbrel [PF]

■ GILTERITINIB

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

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

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Relapsed or refractory Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
 - The condition must not be acute promyelocytic leukaemia, **AND**
 - The condition must be internal tandem duplication (ITD) and/or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, confirmed through a pathology report from an Approved Pathology Authority, **AND**
 - Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 prior to treatment initiation.
- The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.

gilteritinib 40 mg tablet, 84

13093D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	25144.28	42.50	Xospata [LL]

■ GILTERITINIB

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

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Relapsed or refractory Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, following a response to gilteritinib, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- (a) Leukaemic cells in the CSF; or
- (b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or

- (c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or
- (d) Extramedullary leukaemia.

Authority required

Relapsed or refractory Acute Myeloid Leukaemia

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022, **AND**
- Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must have relapsed or been refractory prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be internal tandem duplication (ITD) and/or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, following a response to gilteritinib, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- (a) Leukaemic cells in the CSF; or
- (b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or
- (c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or
- (d) Extramedullary leukaemia.

The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

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

gilteritinib 40 mg tablet, 84

13094E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	25144.28	42.50	Xospata [LL]

▪ **GLATIRAMER ACETATE**

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

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

Note Pharmaceutical benefits that have the form glatiramer acetate 40 mg/mL syringes and pharmaceutical benefits that have the form glatiramer acetate 40 mg/mL pen devices are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

7695

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

6860

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes

10416F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	667.25	42.50	^a Copaxone [TB] ^a GLATIRAMER ACETATE-TEVA [EV]	^a Glatira [JU]

glatiramer acetate 40 mg/mL injection, 12 x 1 mL pen devices

13110B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	667.25	42.50	Copaxone [TB]

■ GOLIMUMAB**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under

'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3428K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1160.64	42.50	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11375Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1160.64	42.50	Simponi [JC]

■ GOLIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops

providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

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

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3426H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1160.64	42.50	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11372M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1160.64	42.50	Simponi [JC]

■ IMATINIB

Note No 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)

13132

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

imatinib 600 mg tablet, 30

12919Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
	1	2	..	978.52	42.50	Imatab [JU]	

■ IMATINIB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**13132**

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

imatinib 400 mg capsule, 30

12723P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	662.67	42.50	^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]	^a IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

11778X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	662.67	42.50	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**13132**

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to

400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

imatinib 100 mg capsule, 60

12722N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	334.91	42.50	^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]	^a IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

11787J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	334.91	42.50	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

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

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

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Authority required

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

imatinib 100 mg capsule, 60

12709X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	334.91	42.50	^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]	^a IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9111M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	334.91	42.50	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

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

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

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

Clinical criteria:

- The condition must be metastatic; OR

- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

imatinib 400 mg capsule, 30

12754G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	662.67	42.50	^a Imatinib-APOTEX [TX] ^a Imatinib GH [GQ]	^a IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9112N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	662.67	42.50	^a Gilmat [CR] ^a IMATINIB RBX [RA]	^a Glivec [AF] ^a Imatinib-Teva [SZ]

■ IMATINIB

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

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

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

Authority required

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The condition must have not achieved a response with this drug at a dose of 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

imatinib 600 mg tablet, 30

12926H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	978.52	42.50	Imatab [JU]

■ INFLIXIMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of

more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply for Initial treatment, Continuing treatment - subcutaneous form

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 treatment with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.

Population criteria:

- Patient must be at least 18 years of age.

infliximab 120 mg/mL injection, 1 mL pen device

12566J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	382.86	42.50	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL syringe

12555T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	382.86	42.50	Remsima SC [EW]

■ INFLIXIMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the

necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

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 (in any form) 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; OR
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

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

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

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

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

infliximab 120 mg/mL injection, 1 mL pen device

12554R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*758.58	42.50	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL syringe

12553Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*758.58	42.50	Remsima SC [EW]

■ INFLIXIMAB**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine

cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

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

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

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

Treatment criteria:

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

Population criteria:

- Patient must be at least 18 years of age.

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

(1) a completed authority prescription form; and

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

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

infliximab 120 mg/mL injection, 1 mL pen device

12577Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*758.58	42.50	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL syringe

12576X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*758.58	42.50	Remsima SC [EW]

▪ **MEDIUM CHAIN TRIGLYCERIDES**

Note From 1 September 2022, the brand K.Quik has replaced the brand Betaquik.

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

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

Authority required (STREAMLINED)

6147

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

Authority required (STREAMLINED)

6191

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have chylous ascites; OR
- Patient must have chylothorax; OR
- Patient must have hyperlipoproteinaemia type 1; OR
- Patient must have long chain fatty acid oxidation disorders; OR
- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

medium chain triglycerides oral liquid, 15 x 225 mL bottles

13108X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*274.76	42.50	K.Quik [VF]

medium chain triglycerides oral liquid, 15 x 225 mL bottles

11444H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*274.76	42.50	Betaquik [VF]

▪ **MOLNUPIRAVIR**

Note No 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)

13201

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

Population criteria:

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)**13155**

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must be moderately to severely immunocompromised, **AND**
- Patient must be at risk of progression to severe disease due to immunocompromised status, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:
 - a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,
 - b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),
 - c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR
2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:
 - a. Chemotherapy or whole body radiotherapy,
 - b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,
 - c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),
 - d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR
3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received rituximab; OR
4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR
5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)**13224**

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**

- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk. For the purpose of administering this restriction, high risk is defined as the presence of at least two of the following conditions:

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m²),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>

Authority required (STREAMLINED)

13156

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least two of the following conditions:

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m²),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>

molnupiravir 200 mg capsule, 40

12910L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1101.39	42.50	Lagevrio [MK]

■ NIRAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuing treatment - first line treatment of a patient requiring a daily dose of 3 capsules

Clinical criteria:

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

niraparib 100 mg capsule, 84

13079J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9873.54	42.50	Zejula [GK]

■ NIRAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuing treatment - first line treatment of a patient requiring a daily dose of up to 2 capsules

Clinical criteria:

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

niraparib 100 mg capsule, 56

13112D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	6636.12	42.50	Zejula [GK]

■ NIRAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial treatment - first line treatment of a patient requiring a daily dose of up to 2 capsules

Clinical criteria:

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
 - Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.
- A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.
- Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

niraparib 100 mg capsule, 56

13089X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	6636.12	42.50	Zejula [GK]

■ NIRAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial treatment - first line treatment of a patient requiring a daily dose of 3 capsules

Clinical criteria:

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
 - Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.
- A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.
- Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

niraparib 100 mg capsule, 84

13092C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9873.54	42.50	Zejula [GK]

■ NIRMATRELVIR (&) RITONAVIR

Caution Nirmatrelvir with ritonavir has significant drug-drug interactions. Please refer to the TGA approved Paxlovid Product Information. Prescribers and dispensers should carefully review a patient's concomitant medications including over-the-counter medications, herbal supplements, and recreational drugs.

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

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

Authority required (STREAMLINED)**13201**

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

Population criteria:

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)**13155**

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must be moderately to severely immunocompromised, **AND**
- Patient must be at risk of progression to severe disease due to immunocompromised status, **AND**

- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:
 - a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,
 - b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),
 - c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR
2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:
 - a. Chemotherapy or whole body radiotherapy,
 - b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,
 - c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),
 - d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR
3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received rituximab; OR
4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR
5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)

13224

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least two of the following conditions:

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m²),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>

Authority required (STREAMLINED)

13156

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least two of the following conditions:

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m²),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>

nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6

12996B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	1113.99	42.50	Paxlovid [HD]

■ OLAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Special Pricing Arrangements apply.

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial treatment - first line treatment

Clinical criteria:

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

olaparib 100 mg tablet, 56

12170M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6630.78	42.50	Lynparza [AP]

olaparib 150 mg tablet, 56

12157W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6630.78	42.50	Lynparza [AP]

■ OXYBUTYNIN

Note Pharmaceutical benefits that have the form oxybutynin chloride 5 mg tablet can be substituted for the form oxybutynin hydrochloride 5 mg tablet in the case of a shortage.

Restricted benefit

Detrusor overactivity

oxybutynin hydrochloride 5 mg tablet, 100

13098J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	25.58	26.89	^a Oxybutynin Chloride (Novitium) [QY]

oxybutynin hydrochloride 5 mg tablet, 100

8039D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	16.09	17.40	^a Ditropan [SW]

■ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses

13100L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*33.08	34.39	Systane [AQ]

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses

13113E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	5	..	*33.08	34.39	Systane [AQ]

■ RUXOLITINIB

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

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

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Authority required

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Authority required

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

ruxolitinib 5 mg tablet, 56

10616R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*4911.28	42.50	Jakavi [NV]

ruxolitinib 15 mg tablet, 56

10615Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4911.28	42.50	Jakavi [NV]

ruxolitinib 20 mg tablet, 56

10617T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4911.28	42.50	Jakavi [NV]

ruxolitinib 10 mg tablet, 56

10927D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4911.28	42.50	Jakavi [NV]

■ RUXOLITINIB

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos). Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- Details (date, unique identifying number/code or provider number) of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and
- A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

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

Authority required

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**

- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- Details (date, unique identifying number/code or provider number) of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and
- A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and
- A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

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

ruxolitinib 5 mg tablet, 56

10614P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*4911.28	42.50	Jakavi [NV]

ruxolitinib 15 mg tablet, 56

10619X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4911.28	42.50	Jakavi [NV]

ruxolitinib 20 mg tablet, 56

10618W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4911.28	42.50	Jakavi [NV]

ruxolitinib 10 mg tablet, 56

10913J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	4911.28	42.50	Jakavi [NV]

■ SONIDEGIB

Caution Sonidegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 20 months and 6 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

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

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

Note Special Pricing Arrangements apply.

Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and

(c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

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

Inappropriate for surgery is defined as:

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

Inappropriate for curative radiotherapy is defined as:

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

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

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Confirmation from the treating doctor that the disease has not progressed; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

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

Inappropriate for surgery is defined as:

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

Inappropriate for curative radiotherapy is defined as:

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

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

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment or Continuing treatment – balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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

sonidegib 200 mg capsule, 30

11304Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7982.71	42.50	Odomzo [RA]

■ SUNITINIB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

Authority required

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must not be resectable, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have previously failed or be intolerant to imatinib mesilate.

Applications for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

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

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.

sunitinib 12.5 mg capsule, 28

9488J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	893.47	42.50	^a Sunitinib Sandoz [SZ]	^a Sutent [PF]

sunitinib 25 mg capsule, 28

9489K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1733.41	42.50	^a ARX-Sunitinib [XT] ^a Sutent [PF]	^a Sunitinib Sandoz [SZ]

sunitinib 37.5 mg capsule, 28

10503T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	2544.16	42.50	^a ARX-Sunitinib [XT] ^a Sutent [PF]	^a Sunitinib Sandoz [SZ]

sunitinib 50 mg capsule, 28

9490L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	3380.39	42.50	^a ARX-Sunitinib [XT] ^a Sutent [PF]	^a Sunitinib Sandoz [SZ]

■ SUNITINIB

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

Note Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug

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

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

Authority required (STREAMLINED)**13153**

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not be resectable, **AND**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

sunitinib 12.5 mg capsule, 28

11266Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	893.47	42.50	^a Sunitinib Sandoz [SZ]	^a Sutent [PF]

sunitinib 25 mg capsule, 28

11253G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1733.41	42.50	^a ARX-Sunitinib [XT] ^a Sutent [PF]	^a Sunitinib Sandoz [SZ]

sunitinib 37.5 mg capsule, 28

11256K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	2544.16	42.50	^a ARX-Sunitinib [XT] ^a Sutent [PF]	^a Sunitinib Sandoz [SZ]

sunitinib 50 mg capsule, 28

11250D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	3380.39	42.50	^a ARX-Sunitinib [XT] ^a Sutent [PF]	^a Sunitinib Sandoz [SZ]

■ TOCILIZUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application

following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11567T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	811.95	42.50	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

10954M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	811.95	42.50	Actemra Subcutaneous Injection [RO]

■ TOCILIZUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR

- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

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

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**

- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11565Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	811.95	42.50	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

10951J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	811.95	42.50	Actemra Subcutaneous Injection [RO]

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Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

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

tofacitinib 5 mg tablet, 56

10511F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1211.08	42.50	Xeljanz [PF]

■ TOFACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under

'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

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

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

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

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

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

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

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

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

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

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

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

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

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

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted

following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the

date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tofacitinib 5 mg tablet, 56

10517M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1211.08	42.50	Xeljanz [PF]

■ UPADACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at

least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must 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.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks 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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

upadacitinib 15 mg modified release tablet, 28

11979L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1271.46	42.50	Rinvoq [VE]

■ UPADACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

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 to DMARD treatment 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 and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must 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.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, conducted within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must 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.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must 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.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or commencement 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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

upadacitinib 15 mg modified release tablet, 28

11989B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1271.46	42.50	Rinvoq [VE]

▪ VEDOLIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14

and 16 will be authorised.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that

biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply - subcutaneous form

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.

vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12620F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1746.45	42.50	Entyvio [TK]

▪ VEDOLIZUMAB**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab, tofacitinib and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab, tofacitinib or vedolizumab at any one time. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, golimumab, infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the Janus kinase (JAK) inhibitor (tofacitinib).

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to start their first cycle as of 1 July 2021. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment after 1 July 2021.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) an adult patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or
- (iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and tofacitinib, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab or infliximab subcutaneous form or vedolizumab subcutaneous form, a minimum of 8 weeks for tofacitinib, and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab intravenous form or vedolizumab intravenous form.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Vedolizumab subcutaneous form only:

initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and infliximab only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the

most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between the intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course (except tofacitinib) will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply - subcutaneous form

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.

vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12647P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1746.45	42.50	Entyvio [TK]

■ **VISMODEGIB**

Caution Vismodegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 24 months and 2 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and
- (b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and
- (c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Inappropriate for surgery is defined as:

- (i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or
- (ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or
- (iii) Medical contraindication to surgery.

Inappropriate for curative radiotherapy is defined as:

- (i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or
- (ii) Limitations due to location of tumour; or
- (iii) Limitations due to cumulative prior radiotherapy dose; or
- (iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (a) Confirmation from the treating doctor that the disease has not progressed; and
- (b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Inappropriate for surgery is defined as:

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

Inappropriate for curative radiotherapy is defined as:

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment or Continuing treatment – balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

vismodegib 150 mg capsule, 28

11070P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7096.28	42.50	Erivedge [RO]

▪ **VORINOSTAT**

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received systemic treatment with chemotherapy, **AND**
- Patient must demonstrate relapsed or chemotherapy-refractory disease, **AND**

- Patient must be ineligible for stem cell transplant, **AND**
 - The treatment must be the sole PBS-subsidised therapy for this condition.
- Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.
- If the application is submitted through HPOS form upload or mail, it must include:
- (a) a completed authority prescription form; and
 - (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

vorinostat 100 mg capsule, 120

11138F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	4463.40	42.50	Zolinza [MK]

▪ **VORINOSTAT**

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

vorinostat 100 mg capsule, 120

11141J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4463.40	42.50	Zolinza [MK]

Highly Specialised Drugs Program (Private Hospital)

▪ ABATACEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply

treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
 Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
 Complex Drugs
 Reply Paid 9826
 HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

abatacept 250 mg injection, 1 vial

9621J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	284.81	Orencia [BQ]

■ CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

9764

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

9695

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

Authority required (STREAMLINED)**13122**

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist.

Authority required (STREAMLINED)**9694**

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

Treatment criteria:

- Must be treated by a nephrologist.

Authority required (STREAMLINED)**9742**

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

ciclosporin 10 mg capsule, 60

6232B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*86.22	Neoral 10 [NV]

ciclosporin 100 mg capsule, 30

6354K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*576.06	^a APO-Ciclosporin [TX] ^a Neoral 100 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 25 mg capsule, 30

6352H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*141.86	^a APO-Ciclosporin [TX] ^a Neoral 25 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 50 mg capsule, 30

6353J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*286.70	^a APO-Ciclosporin [TX] ^a Neoral 50 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 100 mg/mL oral liquid, 50 mL

6125J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*1310.98	Neoral [NV]

■ INFlixIMAB**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a

treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

infliximab 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
11487N	1	..	..	341.36	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

12067

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

infliximab 100 mg injection, 1 vial

11483J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*1008.44	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

6397Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.36	^a Inflectra [PF]	^a Remicade [JC]
					^a Renflexis [OQ]	

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 2 cycles under this restriction.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

lenalidomide 10 mg capsule, 21

12050F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	4752.24	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

12011E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	5534.42	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

12037M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	5976.56	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

12038N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	4543.04	Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

lenalidomide 10 mg capsule, 21

12060R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4752.24	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

12020P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	5534.42	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

12068E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	5976.56	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

12071H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4543.04	Revlimid [CJ]

▪ **LENALIDOMIDE**

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation

Clinical criteria:

- The condition must be newly diagnosed, **AND**
 - The condition must be confirmed by a histological diagnosis, **AND**
 - Patient must be ineligible for a primary stem cell transplantation, **AND**
 - The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.
- The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma, and

(2) confirmation of ineligibility for prior stem cell transplant; and

(3) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients.

Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment until progression in patients initiated on dual combination therapy (this drug and dexamethasone), or, in patients initiated on triple therapy (this drug, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 10 mg capsule, 21

11063G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4752.24	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

11042E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5534.42	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

11055W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5976.56	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

11036W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4543.04	Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with lenalidomide monotherapy in newly diagnosed disease

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma, **AND**
- Patient must not have progressive disease following autologous stem cell transplant (ASCT).

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) the date the autologous stem cell transplant was performed; and

(3) nomination of which disease activity parameters will be used to assess progression.

To enable confirmation of eligibility for treatment, the details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f) of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be as monotherapy.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 5 mg capsule, 28

11966T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6041.44	Revlimid [CJ]

lenalidomide 10 mg capsule, 28

11969Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6320.38	Revlimid [CJ]

lenalidomide 15 mg capsule, 28

11965R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	7363.28	Revlimid [CJ]

▪ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**

- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**

- The treatment must not exceed a total of 4 cycles under this restriction.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 10 mg capsule, 14

12004T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3184.10	Revlimid [CJ]

lenalidomide 15 mg capsule, 14

12069F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3705.55	Revlimid [CJ]

lenalidomide 25 mg capsule, 14

12018M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4000.31	Revlimid [CJ]

lenalidomide 5 mg capsule, 14

12058P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3044.63	Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and
- (2) prior treatments including name(s) of drug(s) and date of most recent treatment cycle; and
- (3) date of prior stem cell transplant or confirmation of ineligibility for prior stem cell transplant; and
- (4) details of the basis of the diagnosis of progressive disease or failure to respond; and
- (5) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma, **AND**
- The treatment must be as monotherapy; OR
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 10 mg capsule, 21

9643M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4752.24	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

9644N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5534.42	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

9645P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5976.56	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

9642L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4543.04	Revlimid [CJ]

▪ **NUSINERSEN**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority required

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood

Clinical criteria:

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing continuing/maintenance treatment initiated through this drug's Initial treatment listing for SMA type IIIB/IIIC in childhood, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

nusinersen 12 mg/5 mL injection, 5 mL vial

13091B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	110047.82	Spinraza [BD]

▪ **NUSINERSEN**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Literature references for various instruments measuring motor function and quality of life in the context of spinal muscular atrophy are:

Revised Upper Limb Module

Mazzone et al. 2017. Revised upper limb module for spinal muscular atrophy: Development of a new module. **Muscle & Nerve** 55(6):869-874

Hammersmith Functional Motor Scale - Expanded

Ramsey et al. 2017. Revised Hammersmith Scale for spinal muscular atrophy: A SMA specific clinical outcome assessment tool. **PLoS ONE** 12(2): e0172346. doi:10.1371/journal.pone.0172346.

6-Minute Walk Test (6MWT)

American Thoracic Society. 2002. ATS statement: Guidelines for the six-minute walk test. **American Journal of Respiratory and Critical Care Medicine** 166(1), pp 111-117

The National Health Foundation of Australia has 6MWT test standardised instructions and recording forms located at: <https://www.heartonline.org.au/resources/documents-and-links#exercise>

SMA Health Index

Zizzi et al. 2021. The Spinal Muscular Atrophy Health Index (SMA-HI): A Novel Outcome for Measuring How a Patient Feels and Functions. **Muscle & Nerve** 63(10), pp 837-844

SMA Functional Rating Scale

Elsheikh et al. 2018. Reliability of Spinal Muscular Atrophy Functional Rating Scale (SMAFRS) in Ambulatory Adults with Spinal Muscular Atrophy. **Neurology** April (15 Supplement) P4.452

Authority required

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in an adult where treatment was initiated in adulthood

Clinical criteria:

- The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; OR
- The treatment must be occurring within the first 104 weeks from the first administered dose, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment that was initiated through the Initial treatment listing for SMA initiated in adulthood, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.

A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.

PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.

Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.

In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFME) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).

nusinersen 12 mg/5 mL injection, 5 mL vial

13045N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	110047.82	Spinraza [BD]

■ NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment in an adult who did not initiate PBS subsidy during childhood

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood, **AND**
- Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19th birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); OR
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

- (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
- (ii) Proximal weakness,
- (iii) Hypotonia,
- (iv) Absence of deep tendon reflexes,
- (v) Failure to gain weight appropriate for age,
- (vi) Any active denervation or chronic neurogenic changes found on electromyography,
- (vii) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

- (1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,
- (2) which of the above (i to vii) (at least 1) were present during childhood,
- (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

nusinersen 12 mg/5 mL injection, 5 mL vial

13064N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	110047.82	Spinraza [BD]

▪ NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Authority required

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment in a child

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must be of an age that is prior to their 19th birthday at the time of this authority application, **AND**
- Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3rd birthday, but before their 19th birthday (SMA type IIIB/IIIC).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); OR
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

- (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
- (ii) Proximal weakness,
- (iii) Hypotonia,
- (iv) Absence of deep tendon reflexes,
- (v) Any active denervation or chronic neurogenic changes found on electromyography,
- (vi) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

- (1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,
- (2) which of the above (i to vi) (at least 1) were present after their 3rd birthday, but before their 19th birthday,
- (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

nusinersen 12 mg/5 mL injection, 5 mL vial

13111C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	110047.82	Spinraza [BD]

■ POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy that is either: (i) lenalidomide monotherapy, (ii) contains lenalidomide, **AND**

- Patient must have undergone or be ineligible for a stem cell transplant.
- Progressive disease is defined as at least 1 of the following:
- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
 - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
 - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
 - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
 - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
 - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
 - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

pomalidomide 3 mg capsule, 14

12668R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6697.82	Pomalyst [CJ]

pomalidomide 4 mg capsule, 14

12661J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6697.82	Pomalyst [CJ]

■ POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment - dual therapy in combination with dexamethasone

Clinical criteria:

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

-
- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
 - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
 - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
 - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
 - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
 - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
 - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with lenalidomide, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide according to the relevant TGA-approved Product Information; and
- (2) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with bortezomib, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to bortezomib according to the relevant TGA-approved Product Information.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment - dual therapy in combination with dexamethasone

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

pomalidomide 3 mg capsule, 21

10417G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	10022.82	Pomalyst [CJ]

pomalidomide 4 mg capsule, 21

10386P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	10022.82	Pomalyst [CJ]

■ RITUXIMAB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

rituximab 500 mg/50 mL injection, 50 mL vial

13095F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*714.60	^a Riximyo [SZ] ^a Truxima [EW]	^a Ruxience [PF]

■ RITUXIMAB

Note Pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 2 x 10 mL vials and pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 10 mL vial are equivalent for the purposes of substitution.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

13096G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*431.90	^a Riximyo [SZ] ^a Truxima [EW]	^a Truxima [EW]

rituximab 100 mg/10 mL injection, 10 mL vial

13109Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	..	..	*431.90	^a Ruxience [PF]

■ SELINEXOR

Caution This drug is a category D drug and must not be given to pregnant women. If selinexor is taken during pregnancy, a teratogenic effect of selinexor in humans cannot be ruled out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 80 mg or 60 mg per week

Clinical criteria:

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy for this condition, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to the following prior treatments for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 80 mg or 60 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 80 mg or 60 mg per week

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

selinexor 20 mg tablet, 16

13099K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	9407.82	Xpovio [TG]

■ SELINEXOR

Caution This drug is a category D drug and must not be given to pregnant women. If selinexor is taken during pregnancy, a teratogenic effect of selinexor in humans cannot be ruled out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 100 mg per week

Clinical criteria:

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy for this condition, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to the following prior treatments for this condition, which must include:
(i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 100 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 100 mg per week

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

selinexor 20 mg tablet, 20

13103P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	11747.82	Xpovio [TG]

▪ **SELINEXOR**

Caution This drug is a category D drug and must not be given to pregnant women. If selinexor is taken during pregnancy, a teratogenic effect of selinexor in humans cannot be ruled out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 160 mg per week

Clinical criteria:

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy for this condition, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to the following prior treatments for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 160 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 160 mg per week

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

selinexor 20 mg tablet, 32

13105R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	18767.82	Xpovio [TG]

■ TOCILIZUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP

submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an

application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 5 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 200 mg/10 mL injection, 10 mL vial

9672C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	219.70	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

9673D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	429.43	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

9671B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	94.01	Actemra [RO]

Highly Specialised Drugs Program (Public Hospital)

▪ ABATACEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply

treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
 Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
 Complex Drugs
 Reply Paid 9826
 HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

abatacept 250 mg injection, 1 vial

5605B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	266.34	Orencia [BQ]

■ CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

6643

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

6660

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

Authority required (STREAMLINED)**13168**

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist.

Authority required (STREAMLINED)**6631**

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

Treatment criteria:

- Must be treated by a nephrologist.

Authority required (STREAMLINED)**6638**

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

ciclosporin 10 mg capsule, 60

5632K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*74.40	Neoral 10 [NV]

ciclosporin 100 mg capsule, 30

5636P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*546.40	^a APO-Ciclosporin [TX] ^a Neoral 100 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 25 mg capsule, 30

5634M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*128.88	^a APO-Ciclosporin [TX] ^a Neoral 25 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 50 mg capsule, 30

5635N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*268.16	^a APO-Ciclosporin [TX] ^a Neoral 50 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 100 mg/mL oral liquid, 50 mL

5633L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*1263.16	Neoral [NV]

■ INFliximab**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a

treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

infliximab 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
11481G	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

12075

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

infliximab 100 mg injection, 1 vial

11490R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*962.13	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

5757B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**

- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**

- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients.

Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should

be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

lenalidomide 10 mg capsule, 21

12061T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4704.42	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

12062Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	5486.60	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

12059Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	5928.74	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

12034J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4495.22	Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 2 cycles under this restriction.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

lenalidomide 10 mg capsule, 21

12057N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	4704.42	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

12062W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	5486.60	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

12036L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	5928.74	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

12039P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	4495.22	Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma, and
- (2) confirmation of ineligibility for prior stem cell transplant; and
- (3) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment until progression in patients initiated on dual combination therapy (this drug and dexamethasone), or, in patients initiated on triple therapy (this drug, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
 (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 10 mg capsule, 21

11064H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4704.42	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

11062F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5486.60	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

11041D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5928.74	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

11029L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4495.22	Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with lenalidomide monotherapy in newly diagnosed disease

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma, **AND**
- Patient must not have progressive disease following autologous stem cell transplant (ASCT).

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) the date the autologous stem cell transplant was performed; and

(3) nomination of which disease activity parameters will be used to assess progression.

To enable confirmation of eligibility for treatment, the details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f) of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must be as monotherapy.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 5 mg capsule, 28

11967W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	5993.62	Revlimid [CJ]

lenalidomide 10 mg capsule, 28

11968X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6272.56	Revlimid [CJ]

lenalidomide 15 mg capsule, 28

11964Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	7315.46	Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**

- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**

- The treatment must not exceed a total of 4 cycles under this restriction.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 10 mg capsule, 14

12070G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3136.28	Revlimid [CJ]

lenalidomide 15 mg capsule, 14

12012F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3657.73	Revlimid [CJ]

lenalidomide 25 mg capsule, 14

12019N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3952.49	Revlimid [CJ]

lenalidomide 5 mg capsule, 14

12035K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	2996.81	Revlimid [CJ]

▪ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and
- (2) prior treatments including name(s) of drug(s) and date of most recent treatment cycle; and
- (3) date of prior stem cell transplant or confirmation of ineligibility for prior stem cell transplant; and
- (4) details of the basis of the diagnosis of progressive disease or failure to respond; and
- (5) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system

(see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma, **AND**
- The treatment must be as monotherapy; OR
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 10 mg capsule, 21

5784K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4704.42	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

5785L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5486.60	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

5786M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5928.74	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

5783J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4495.22	Revlimid [CJ]

■ **NUSINERSEN**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority required

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood

Clinical criteria:

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing continuing/maintenance treatment initiated through this drug's Initial treatment listing for SMA type IIIB/IIIC in childhood, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

nusinersen 12 mg/5 mL injection, 5 mL vial

13084P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	110000.00	Spinraza [BD]

■ NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment in an adult who did not initiate PBS subsidy during childhood

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood, **AND**
- Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19th birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); OR
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

- (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
- (ii) Proximal weakness,
- (iii) Hypotonia,
- (iv) Absence of deep tendon reflexes,
- (v) Failure to gain weight appropriate for age,
- (vi) Any active denervation or chronic neurogenic changes found on electromyography,
- (vii) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

- (1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,
- (2) which of the above (i to vii) (at least 1) were present during childhood,
- (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

nusinersen 12 mg/5 mL injection, 5 mL vial

13052Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	110000.00	Spinraza [BD]

■ NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Literature references for various instruments measuring motor function and quality of life in the context of spinal muscular atrophy are:

Revised Upper Limb Module

Mazzone et al. 2017. Revised upper limb module for spinal muscular atrophy: Development of a new module. **Muscle & Nerve** 55(6):869-874

Hammersmith Functional Motor Scale - Expanded

Ramsey et al. 2017. Revised Hammersmith Scale for spinal muscular atrophy: A SMA specific clinical outcome assessment tool. **PLoS ONE** 12(2): e0172346. doi:10.1371/journal.pone.0172346.

6-Minute Walk Test (6MWT)

American Thoracic Society. 2002. ATS statement: Guidelines for the six-minute walk test. **American Journal of Respiratory and Critical Care Medicine** 166(1), pp 111-117

The National Heart Foundation of Australia has 6MWT test standardised instructions and recording forms located at:

<https://www.heartonline.org.au/resources/documents-and-links#exercise>

SMA Health Index

Zizzi et al. 2021. The Spinal Muscular Atrophy Health Index (SMA-HI): A Novel Outcome for Measuring How a Patient Feels and Functions. **Muscle & Nerve** 63(10), pp 837-844

SMA Functional Rating Scale

Elsheikh et al. 2018. Reliability of Spinal Muscular Atrophy Functional Rating Scale (SMAFRS) in Ambulatory Adults with Spinal Muscular Atrophy. **Neurology** April (15 Supplement) P4.452

Authority required

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in an adult where treatment was initiated in adulthood

Clinical criteria:

- The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; OR
- The treatment must be occurring within the first 104 weeks from the first administered dose, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment that was initiated through the Initial treatment listing for SMA initiated in adulthood, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.

A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.

PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.

Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.

In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFMSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).

nusinersen 12 mg/5 mL injection, 5 mL vial

13068T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	110000.00	Spinraza [BD]

■ NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Authority required

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment in a child

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must be of an age that is prior to their 19th birthday at the time of this authority application, **AND**
- Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3rd birthday, but before their 19th birthday (SMA type IIIB/IIIC).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); OR
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

- (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
- (ii) Proximal weakness,
- (iii) Hypotonia,
- (iv) Absence of deep tendon reflexes,
- (v) Any active denervation or chronic neurogenic changes found on electromyography,
- (vi) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

- (1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,
- (2) which of the above (i to vi) (at least 1) were present after their 3rd birthday, but before their 19th birthday,
- (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

nusinersen 12 mg/5 mL injection, 5 mL vial

13083N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	110000.00	Spinraza [BD]

■ POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy that is either: (i) lenalidomide monotherapy, (ii) contains lenalidomide, **AND**
- Patient must have undergone or be ineligible for a stem cell transplant.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

pomalidomide 3 mg capsule, 14

12666P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6650.00	Pomalyst [CJ]

pomalidomide 4 mg capsule, 14

12665N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6650.00	Pomalyst [CJ]

▪ **POMALIDOMIDE**

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment - dual therapy in combination with dexamethasone

Clinical criteria:

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**

- Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with lenalidomide, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide according to the relevant TGA-approved Product Information; and
- (2) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with bortezomib, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to bortezomib according to the relevant TGA-approved Product Information.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment - dual therapy in combination with dexamethasone

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

pomalidomide 3 mg capsule, 21

10406Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	9975.00	Pomalyst [CJ]

pomalidomide 4 mg capsule, 21

10387Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	9975.00	Pomalyst [CJ]

▪ RITUXIMAB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

rituximab 500 mg/50 mL injection, 50 mL vial

13101M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*679.60	^a Riximyo [SZ] ^a Truxima [EW]	^a Ruxience [PF]

▪ RITUXIMAB

Note Pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 2 x 10 mL vials and pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 10 mL vial are equivalent for the purposes of substitution.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

13082M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*407.76	^a Riximyo [SZ]	^a Truxima [EW]

rituximab 100 mg/10 mL injection, 10 mL vial

13088W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	..	..	*407.76	^a Ruxience [PF]

▪ SELINEXOR

Caution This drug is a category D drug and must not be given to pregnant women. If selinexor is taken during pregnancy, a teratogenic effect of selinexor in humans cannot be ruled out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 80 mg or 60 mg per week

Clinical criteria:

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy for this condition, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to the following prior treatments for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 80 mg or 60 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 80 mg or 60 mg per week

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

selinexor 20 mg tablet, 16

13085Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	9360.00	Xpovio [TG]

■ SELINEXOR

Caution This drug is a category D drug and must not be given to pregnant women. If selinexor is taken during pregnancy, a teratogenic effect of selinexor in humans cannot be ruled out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 100 mg per week

Clinical criteria:

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy for this condition, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to the following prior treatments for this condition, which must include:
(i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 100 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 100 mg per week

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

selinexor 20 mg tablet, 20

13086R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	11700.00	Xpovio [TG]

■ SELINEXOR

Caution This drug is a category D drug and must not be given to pregnant women. If selinexor is taken during pregnancy, a teratogenic effect of selinexor in humans cannot be ruled out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 160 mg per week

Clinical criteria:

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy for this condition, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to the following prior treatments for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 160 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 160 mg per week

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

selinexor 20 mg tablet, 32

13104Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	18720.00	Xpovio [TG]

■ **TOCILIZUMAB**

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy 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 all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had

insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 5 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 200 mg/10 mL injection, 10 mL vial

9658H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

9659J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

9657G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]